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 AND EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38915

IDEAYA Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-4268251**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7000 Shoreline Court, Suite 350 **South San Francisco, California**	**94080**
(Address of principal executive offices)	**(Zip Code)**

(650) 443-6209
(telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**IDYA**	**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 ☒

As of November 6, 2020, the registrant had 29,069,719 shares of common stock, $0.0001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than statements of historical facts contained in this Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report on Form 10-Q entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- our status as a development-stage company and our expectation to incur losses in the future;
- our future capital needs and our need to raise additional funds;
- our ability to build a pipeline of product candidates and develop and commercialize drugs;
- our unproven approach to therapeutic intervention;
- our ability to enroll patients and volunteers in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- our ability to establish our own manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- the success of the collaboration agreement with GSK and our dependence on the development and marketing efforts of GSK for certain of our programs;
- our expectations about the impact of natural disasters and public health epidemics, such as the COVID-19 pandemic, on our business, results of operations and financial condition;
- our ability to protect and enforce our intellectual property rights;
- federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates;
- the timing of clinical trials and the likelihood of regulatory filings and approvals;
- our ability to obtain and retain key executives and attract and retain qualified personnel; and
- our ability to successfully manage our growth.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not occur or be achieved, and actual results could differ materially from those projected in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

IDEAYA Biosciences, Inc.
Form 10-Q for Quarterly Period Ended September 30, 2020

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ITEM 1. FINANCIAL STATEMENTS (UNAUDITED).

IDEAYA Biosciences, Inc.
Condensed Balance Sheets
(*in thousands, except share and per share amounts*)
(*Unaudited*)

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 81,238	$ 34,067
Short-term marketable securities	197,445	64,889
Prepaid expenses and other current assets	2,654	2,698
Total current assets	281,337	101,654
Restricted cash	106	106
Long-term marketable securities	10,158	1,526
Property and equipment, net	4,095	4,642
Right-of-use assets	5,515	5,057
Other non-current assets	173	16
Total assets	$ 301,384	$ 113,001
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,405	$ 709
Accrued liabilities	6,390	5,023
Contract liability	44,847	—
Lease liabilities	1,502	1,145
Other current liabilities	29	63
Total current liabilities	54,173	6,940
Long-term contract liability	46,186	—
Long-term lease liabilities	5,584	5,627
Other non-current liabilities	12	34
Total liabilities	105,955	12,601
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019; no shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 29,066,161 and 20,339,461 shares issued and outstanding as of September 30, 2020 and December 31, 2019	3	2
Additional paid-in capital	317,242	192,824
Accumulated other comprehensive income	35	65
Accumulated deficit	(121,851)	(92,491)
Total stockholders' equity	195,429	100,400
Total liabilities and stockholders' equity	$ 301,384	$ 113,001

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

IDEAYA Biosciences, Inc.
Condensed Statements of Operations and Comprehensive Loss
(*in thousands, except share and per share amounts*)
(*Unaudited*)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ 8,967	$ —	$ 8,967	$ —
Total revenue	8,967	—	8,967	—
Operating expenses				
Research and development	10,025	8,923	27,647	25,778
General and administrative	3,938	2,700	11,384	7,174
Total operating expenses	13,963	11,623	39,031	32,952
Loss from operations	(4,996)	(11,623)	(30,064)	(32,952)
Interest income and other income (expense), net	70	654	704	1,758
Net loss	$ (4,926)	$ (10,969)	$ (29,360)	$ (31,194)
Change in unrealized (losses) gains on marketable securities	(22)	41	(30)	109
Comprehensive loss	$ (4,948)	$ (10,928)	$ (29,390)	$ (31,085)
Net loss per common share, basic and diluted	$ (0.17)	$ (0.54)	$ (1.26)	$ (3.15)
Weighted average number of common shares outstanding used in computing net loss per share, basic and diluted	28,396,670	20,158,223	23,235,218	9,895,574

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

IDEAYA Biosciences, Inc.
Condensed 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
Balances as of June 30, 2020	27,184,824	$ 3	$ 288,923	$ 57	$ (116,925)	$ 172,058
Issuance of common stock upon follow-on public offering, net of issuance costs	500,000	—	7,040	—	—	7,040
Issuance of common stock in private placement, net of issuance costs	1,333,333	—	19,988	—	—	19,988
Issuance of common stock upon exercise of stock options	53,353	—	297	—	—	297
Repurchase of early exercised shares	(5,349)	—	—	—	—	—
Vesting of early exercised common stock options	—	—	13	—	—	13
Stock-based compensation	—	—	981	—	—	981
Other comprehensive loss	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	(4,926)	(4,926)
Balances as of September 30, 2020	29,066,161	$ 3	$ 317,242	$ 35	$ (121,851)	$ 195,429
Balances as of June 30, 2019	20,268,103	$ 2	$ 191,310	$ 37	$ (70,741)	$ 120,608
Issuance of common stock upon exercise of stock options	62,501	—	190	—	—	190
Repurchase of early exercised shares	(2,362)	—	—	—	—	—
Vesting of early exercised common stock options and restricted stock	—	—	18	—	—	18
Stock-based compensation	—	—	518	—	—	518
Other comprehensive income	—	—	—	41	—	41
Net loss	—	—	—	—	(10,969)	(10,969)
Balances as of September 30, 2019	20,328,242	$ 2	$ 192,036	$ 78	$ (81,710)	$ 110,406

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

IDEAYA Biosciences, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(*in thousands, except share amounts*)
(*Unaudited*)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2019	—	$ —	20,339,461	$ 2	$ 192,824	$ 65	$ (92,491)	$ 100,400
Issuance of common stock upon follow-on public offering, net of issuance costs	—	—	7,166,667	1	100,663	—	—	100,664
Issuance of common stock in private placement, net of issuance costs	—	—	1,333,333		19,988	—	—	19,988
Issuance of common stock upon exercise of stock options	—	—	218,724	—	1,028	—	—	1,028
Employee stock purchase plan (ESPP) purchase	—		18,494	—	132	—	—	132
Repurchase of early exercised shares	—	—	(10,518)	—	—	—	—	—
Vesting of early exercised common stock options	—	—	—	—	44	—	—	44
Stock-based compensation	—	—	—	—	2,563	—	—	2,563
Other comprehensive loss	—	—	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	—	—	(29,360)	(29,360)
Balances as of September 30, 2020	—	$ —	29,066,161	$ 3	$ 317,242	$ 35	$ (121,851)	$ 195,429
Balances as of December 31, 2018	13,139,794	$ 138,391	1,335,690	$ —	$ 1,599	$ (31)	$ (50,516)	$ (48,948)
Conversion of redeemable convertible preferred stock into common stock	(13,139,794)	(138,391)	13,139,794	1	138,390	—	—	138,391
Issuance of common stock upon initial public offering, net of issuance costs	—	—	5,750,000	1	50,246	—	—	50,247
Issuance of common stock upon exercise of stock options	—	—	114,890	—	261	—	—	261
Early exercised common stock options	—	—	2,112	—	—			—
Repurchase of early exercised shares	—	—	(14,244)	—	—	—	—	—
Vesting of early exercised common stock options and restricted stock	—	—	—	—	91	—	—	91
Stock-based compensation	—	—	—	—	1,449	—	—	1,449
Other comprehensive income	—	—	—	—	—	109	—	109
Net loss	—	—	—	—	—	—	(31,194)	(31,194)
Balances as of September 30, 2019	—	$ —	20,328,242	$ 2	$ 192,036	$ 78	$ (81,710)	$ 110,406

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

IDEAYA Biosciences, Inc.
Condensed Statements of Cash Flows
(*in thousands*)
(*Unaudited*)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (29,360)	$ (31,194)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	1,020	915
Net amortization of premiums and discounts on marketable securities	160	(451)
Stock-based compensation	2,563	1,449
Loss on sale of property and equipment	2	14
Realized gain on marketable securities	(3)	(7)
Changes in assets and liabilities		
Prepaid expenses and other assets	(81)	(2,071)
Right-of-use assets	(459)	870
Accounts payable	684	(153)
Accrued and other liabilities	1,186	1,000
Contract liabilities	91,033	—
Lease liabilities	314	(979)
Net cash provided by (used in) operating activities	67,059	(30,607)
Cash flows from investing activities		
Purchases of property and equipment, net	(314)	(1,137)
Purchases of marketable securities	(214,412)	(86,117)
Maturities of marketable securities	73,037	67,538
Sales of marketable securities	—	18,094
Net cash used in investing activities	(141,689)	(1,622)
Cash flows from financing activities		
Proceeds from issuance of common stock upon public offering, net of issuance costs	100,664	50,321
Proceeds from issuance of common stock in private placement, net of issuance costs	19,988	—
Proceeds from exercise of common stock options, net of repurchases	1,017	251
Proceeds from ESPP purchase	132	—
Net cash provided by financing activities	121,801	50,572
Net increase in cash, cash equivalents and restricted cash	47,171	18,343
Cash, cash equivalents and restricted cash		
Cash, cash equivalents and restricted cash, at beginning of period	34,173	20,611
Cash, cash equivalents and restricted cash, at end of period	$ 81,344	$ 38,954
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 81,238	$ 38,848
Restricted cash	$ 106	$ 106
Cash, cash equivalents and restricted cash	$ 81,344	$ 38,954
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 1	$ 1
Cash paid for interest	$ 62	$ 69
Supplemental non-cash investing and financing activities:		
Vesting of early exercised options and restricted stock	$ 44	$ 91
Purchases of property and equipment in accounts payable and accrued liabilities	$ 161	$ 11
Unpaid offering costs	$ 31	$ —
Conversion of redeemable convertible preferred stock into common stock	$ —	$ 138,391

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

1. Organization

Description of the Business

IDEAYA Biosciences, Inc. (the "Company") is an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. The Company is headquartered in South San Francisco, California and was incorporated in the State of Delaware in June 2015. To date, the Company has been primarily engaged in business planning, research, development, recruiting and raising capital.

Follow-On Offering

On June 22, 2020, the Company completed an underwritten public offering and sold and issued 6,666,667 shares of common stock at a price to the public of $15.00 per share for gross proceeds of $100.0 million. On July 22, 2020, the Company sold and issued an additional 500,000 shares of common stock upon the exercise of the overallotment option by the underwriters for gross proceeds of $7.5 million. The aggregate net proceeds to the Company were $100.7 million after deducting underwriting discounts and commissions and other offering costs.

Private Placement

The Company entered into a stock purchase agreement with Glaxo Group Limited, or GGL on June 17, 2020, pursuant to which, on August 3, 2020, the Company sold 1,333,333 shares at a price of $15.00 per shares to GGL for net proceeds of $20.0 million in a private placement.

Liquidity

The Company has incurred significant losses and negative cash flows from operations in all periods since inception and had an accumulated deficit of $121.9 million as of September 30, 2020. The Company has historically financed its operations primarily through the sale of convertible notes, redeemable convertible preferred stock and common stock, and payments received from its collaboration arrangement. To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any revenue from commercial products since inception. Management expects operating losses to continue and increase for the foreseeable future, as the Company progresses into clinical development activities for its lead product candidates. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed under Risks and Uncertainties in Note 2. While the Company has been able to raise multiple rounds of financing, there can be no assurance that in the event the Company requires additional financing, such financing will be available on terms which are favorable or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

As of September 30, 2020, the Company had cash, cash equivalents and marketable securities of $288.8 million. Management believes that the Company's current cash, cash equivalents and marketable securities will be sufficient to fund its planned operations for at least 12 months from the date of the issuance of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed financial statements and accompanying notes have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). Certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2019 has been derived from the audited financial statements at that date but does not include all of the information required by GAAP for complete financial statements. The accompanying balance sheet as of September 30, 2020, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and September 30, 2019, the statements of stockholders' equity for the three months ended September 30, 2020 and September 30, 2019, the statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the nine months ended September 30, 2020 and September 30, 2019 and the

statements of cash flows for the nine months ended September 30, 2020 and September 30, 2019 are unaudited. In the opinion of management, the unaudited data reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2020, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2020 and September 30, 2019 and its cash flows for the nine months ended September 30, 2020 and September 30, 2019. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2020 and September 30, 2019 are also unaudited. The results for the three and nine months ended September 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods or any future year or period.

The accompanying interim unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2019, which are included in the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2020 (the "Form 10-K").

Reverse Stock Split

In May 2019, the Company's board of directors approved a 1-for-10.2564 reverse stock split of the Company's common stock and redeemable convertible preferred stock, which was effected on May 21, 2019. The par value and authorized shares of the common stock and redeemable convertible preferred stock were not adjusted as a result of the reverse stock split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in these financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

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 and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. Such estimates include useful lives of property and equipment, determination of the discount rate for operating leases, accruals for research and development activities, revenue recognition, stock-based compensation, and income taxes. Actual results could differ from those estimates.

Risks and Uncertainties

The Company operates in a dynamic and highly competitive industry and is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, contract manufacturer, contract research organizations and collaboration partners, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies and clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting. The Company believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials and collaboration activities; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company based on intellectual property, patent, product, regulatory, or other factors; and the Company's ability to attract and retain employees necessary to support its growth.

Products developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that the products will receive the necessary approvals, or that any approved products will be commercially viable. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval, it could have a materially adverse impact on the Company. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Beginning in late 2019, the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, has evolved into a global pandemic. The extent of the impact of the coronavirus outbreak on the Company's business will depend on certain developments, including the duration and spread of the outbreak and the extent and severity of the impact on the Company's clinical trial activities, research activities and suppliers, all of which are uncertain and cannot be predicted. At this point, the extent to which the coronavirus outbreak may materially impact the Company's financial condition, liquidity or results of operations is uncertain.

The Company has expended and will continue to expend substantial funds to complete the research, development and clinical testing of product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. The Company may require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs which would materially and adversely affect its business, financial condition and operations.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and marketable securities. Substantially all the Company's cash is held by one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company's investment policy addresses credit ratings, diversification, and maturity dates. The Company invests its cash equivalents and marketable securities in money market funds, U.S. government securities, commercial paper, and corporate bonds. The Company limits its credit risk associated with cash equivalents and marketable securities by placing them with banks and institutions it believes are highly creditworthy and in highly rated investments and, by policy, limits the amount of credit exposure with any one commercial issuer. The Company has not experienced any credit losses on its deposits of cash, cash equivalents or marketable securities.

Summary of Significant Accounting Policies

There have been no material changes in the accounting policies from those disclosed in the financial statements and the related notes included in the Form 10-K.

Revenue Recognition

The Company follows Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation.

The Company applies the five-step model to contracts when (1) parties have approved the contract and are committed to performing respective obligations, (2) the Company can identify each party's rights regarding the goods or services to be transferred, (3) the Company can identify the payment terms for the goods or services to be transferred, (4) the contract has commercial substance, and (5) it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract and determines the performance obligations by assessing whether each promised good or service is distinct. Goods or services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligations when (or as) the performance obligations are satisfied. The Company constrains its estimate of the transaction price up to the amount (the "variable consideration constraint") that a significant reversal of recognized revenue is not probable.

Licenses of intellectual property: If a license to the Company's intellectual property is determined to be distinct from the other promised goods or services identified in an arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license at the point in time when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other goods or services, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress toward satisfying the performance obligation for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition.

Customer options for additional goods or services: If a contract contains customer options that allow the customer to acquire additional goods or services, including a license to the Company's intellectual property, the goods and services underlying the customer options are evaluated to determine whether they are deemed to represent a material right. In determining whether the customer option has a material right, the Company assesses whether there is an option to acquire additional goods or services at a discount. If the customer option is determined not to represent a material right, the option is not considered to be a performance obligation. If the customer option is determined to represent a material right, the material right is recognized as a separate performance obligation. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until the option is exercised.

Milestone payments: At the inception of each arrangement or amendment that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. ASC 606 prescribes two methods to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. If it is probable that a significant revenue reversal would not occur when the uncertainty associated with the milestone is resolved, the associated milestone value is included in the transaction price. Milestone payments that are highly susceptible to factors outside the Company's influence, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. If there is more than one performance obligation, the transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees are recorded as contract liabilities upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. Amounts payable to the Company and not yet billed to the collaboration partner are recorded as contract assets. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Contractual cost sharing payments received from a customer or collaboration partner are accounted for as variable consideration. The Company includes an expected value in the transaction price. Contractual cost sharing payments made to a customer or collaboration partner are accounted for as a reduction to the transaction price if such payments are not related to distinct goods or services received from the customer or collaboration partner.

Contracts may be amended to account for changes in contract specifications and requirements. Contract modifications exist when the amendment either creates new, or changes existing, enforceable rights and obligations. When contract modifications create new performance obligations and the increase in consideration approximates the standalone selling price for goods and services related to such new performance obligations as adjusted for specific facts and circumstances of the contract, the modification is accounted for as a separate contract. If a contract modification is not accounted for as a separate contract, the Company accounts for the promised goods or services not yet transferred at the date of the contract modification (the remaining promised goods or services) prospectively, as if it were a termination of the existing contract and the creation of a new contract, if the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification. The Company accounts for a contract modification as if it were a part of the existing contract if the remaining goods or services are not distinct and, therefore, form part of a single performance obligation that is partially satisfied at the date of the contract modification. In such case the effect that the contract modification has on the transaction price, and on the entity's measure of progress toward complete satisfaction of the performance obligation, is recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) at the date of the contract modification (the adjustment to revenue is made on a cumulative catch-up basis).

Upfront payment contract liabilities resulting from the Company's license and collaboration agreements do not represent a financing component as the payment is not financing the transfer of goods and services, and the technology underlying the licenses granted reflects research and development expenses already incurred by the Company. As such, the Company does not adjust its revenues for the effects of a significant financing component.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, stock options and restricted stock that is subject to repurchase at the original purchase price are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. The Company considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities, because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") under its accounting standard codifications ("ASC") or other standard setting bodies and adopted by the Company as of the specified effective date, unless otherwise discussed below.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. ASU 2018-13 removes the requirement to disclose: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this ASU on January 1, 2020. The adoption did not result in a material impact on the Company's financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* ASU 2018-15 requires that certain implementation costs incurred in a cloud computing arrangement be deferred and recognized over the term of the arrangement. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this ASU on January 1, 2020, using the prospective transition method. The adoption did not result in a material impact on the Company's financial statements and related disclosures.

In November 2018, the FASB issued ASU 2018-18, *Collaborative arrangements (Topic 808)—Clarifying the interaction between Topic 808 and Topic 606*. ASU 2018-18 (i) clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account, (ii) adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606, and (iii) requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. For public business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this ASU on January 1, 2020. The adoption did not result in a material impact on the Company's financial statements and related disclosures.

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The FASB subsequently issued supplemental guidance to ASC 326 within ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*, ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)* and ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. ASU 2019-10 extended the effectiveness of Topic 326 for smaller reporting companies until fiscal years beginning after December 31, 2020. Early adoption is permitted. The Company is currently evaluating the impact the adoption of these ASUs will have on its financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and improves consistent application of and simplifies GAAP for other areas of Topic 740 by clarifying existing guidance. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its financial statements and related disclosures.

3. Fair Value Measurement and Marketable Securities

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

As of September 30, 2020, financial assets measured and recognized at fair value are as follows (in thousands):

		September 30, 2020			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Assets					
U.S. government securities	Level 1	$ 100,011	$ 8	$ —	$ 100,019
Corporate bonds	Level 2	63,624	40	(14)	63,650
Commercial paper	Level 2	43,934	—	—	43,934
Marketable securities		207,569	48	(14)	207,603
Money market funds(1)	Level 1	81,135	—	—	81,135
Total fair value of assets		$ 288,704	$ 48	$ (14)	$ 288,738

(1) Included in cash and cash equivalents on the balance sheet

As of December 31, 2019, financial assets measured and recognized at fair value are as follows (in thousands):

		December 31, 2019			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Assets					
U.S. government securities	Level 1	$ 24,973	$ 32	$ —	$ 25,005
Corporate bonds	Level 2	39,185	37	(4)	39,218
Commercial paper	Level 2	2,192	—	—	2,192
Marketable securities		66,350	69	(4)	66,415
Money market funds(1)	Level 1	34,008	—	—	34,008
Total fair value of assets		$ 100,358	$ 69	$ (4)	$ 100,423

(1) Included in cash and cash equivalents on the balance sheet

As of September 30, 2020, all marketable securities had a remaining maturity of one year or less, except for corporate bonds with a fair value of $10.2 million that had maturities of one to two years. As of December 31, 2019, all marketable securities had a remaining maturity of one year or less, except for corporate bonds with a fair value of $1.5 million that had maturities of one to two years. There were no financial liabilities measured and recognized at fair value as of September 30, 2020 and December 31, 2019.

4. Balance Sheet Components

Property and Equipment, Net

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

	Useful Life (In Years)	September 30, 2020	December 31, 2019
Laboratory equipment	5	$ 4,336	$ 4,034
Computer equipment	3	117	117
Software	3	118	118
Leasehold improvements	Shorter of useful life or lease term	2,636	2,581
Furniture and fixtures	5	421	308
Total property and equipment		7,628	7,158
Less: Accumulated depreciation and amortization		(3,533)	(2,516)
Property and equipment, net		$ 4,095	$ 4,642

Depreciation and amortization expense was $0.3 million and $0.3 million for the three months ended September 30, 2020 and September 30, 2019, respectively, and $1.0 million and $0.9 million for the nine months ended September 30, 2020 and September 30, 2019, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued research and development expenses	$ 3,217	$ 2,787
Accrued salaries and benefits	2,425	1,733
Legal and professional fees	601	457
Other	147	46
Accrued liabilities	$ 6,390	$ 5,023

5. Operating Leases

The Company leases its laboratory and office facilities in South San Francisco, California under a non-cancelable operating lease with expiration date in July 2024 (“Original Lease”).

On September 30, 2019, the Company and the landlord of the laboratory and office facilities in South San Francisco entered into a second amendment (“Second Amendment”) to lease additional office spaces at the same location. The Company accounts for the Second Amendment as a separate contract and recognized a related right-of-use (“ROU”) asset and lease liability of $1.2 million on the lease commencement date in August 2020.

The maturities of operating lease liabilities as of September 30, 2020 are as follows (in thousands):

As of September 30, 2020	Operating Leases
Remaining fiscal 2020	$ 478
2021	1,930
2022	1,982
2023	2,036
2024	1,647
Total lease payments	8,073
Less: Interest	(987)
Present value of lease liabilities	$ 7,086
Amounts recognized on the balance sheet	
Current lease liabilities	$ 1,502
Long-term lease liabilities	5,584
Total lease liabilities	$ 7,086

Operating lease cost was $0.4 million and $0.4 million for the three months ended September 30, 2020 and September 30, 2019, respectively, and $1.1 million and $1.2 million for the nine months ended September 30, 2020 and September 30, 2019, respectively.

As of September 30, 2020, the ROU assets of $5.5 million are included in non-current assets on the balance sheet, and lease liabilities of $7.1 million are included in current liabilities and non-current liabilities on the balance sheet.

As of September 30, 2020, the remaining term for the operating lease in South San Francisco, California is 3.8 years, and the discount rate used to measure the lease liability for such operating lease upon recognition is 7.0% for the Original Lease and 6.0% for the Second Amendment.

During the nine months ended September 30, 2020, cash paid for amounts included in operating lease liabilities of $1.2 million is included in cash flows from operating activities on the statement of cash flows.

6. Commitments and Contingencies

Contingencies

From time to time, the Company may be involved in litigation related to claims that arise in the ordinary course of its business activities. The Company accrues for these matters when it is probable that future expenditures will be made and these expenditures can be reasonably estimated. As of September 30, 2020, the Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's financial position, results of operations or cash flows.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business with vendors, clinical trial sites and other parties. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the fair value of these agreements is not material.

7. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the nine months ended September 30, 2020 and September 30, 2019 as it has incurred net losses since inception. In addition, the net deferred tax assets generated from net operating losses are fully offset by a valuation allowance as the Company believes it is not more likely than not that the benefit will be realized.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was enacted and signed into law and GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. The CARES Act includes changes to the tax provisions that benefits business entities, and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act. The tax relief measures for businesses in the CARES Act include a five-year net operating loss carryback for certain net operating losses, suspension of the annual deduction limitation of 80% of taxable income for certain net operating losses, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. The CARES Act also provides other non-tax benefits to assist those impacted by the pandemic. The Company evaluated the impact of the CARES Act and determined that there is no material impact to the income tax provision for the quarter ended September 30, 2020.

On June 29, 2020, California Assembly Bill 85 (AB 85) was signed into law, which suspends the use of net operating losses and limits the use of research tax credits for 2020, 2021 and 2022, respectively. The Company evaluated the impact of AB 85 and determined that the new legislation did not materially impact the Company's income tax provision for the quarter ended September 30, 2020.

8. Common Stock

As of September 30, 2020 and December 31, 2019, the Company's certificate of incorporation authorized the Company to issue 300,000,000 shares of common stock at a par value of $0.0001 per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors. As of September 30, 2020 and December 31, 2019, no dividends have been declared to date.

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

	September 30, 2020	December 31, 2019
Exercise of outstanding options under the 2015 and 2019 Plans	2,592,537	1,962,332
Issuance of common stock options under the 2019 Plan	1,011,913	1,036,746
Issuance of common stock options under the Employee Stock Purchase Plan	379,900	195,000
Total	3,984,350	3,194,078

9. Stock-Based Compensation

2019 Incentive Award Plan

In May 2019, the Company's board of directors adopted and the Company's stockholders approved the 2019 Incentive Award Plan (the "2019 Plan"), under which the Company may grant cash and equity-based incentive awards to the Company's employees, consultants and directors. Following the effectiveness of the 2019 Plan, the Company will not make any further grants under the 2015 Equity Incentive Plan (the "2015 Plan"). However, the 2015 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2015 Plan that are forfeited or lapse unexercised and which following the effective date of the 2019 Plan are not issued under the 2015 Plan will be available for issuance under the 2019 Plan.

Options granted under the 2019 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees and consultants.

The exercise price of an ISO and NSO shall not be less than 100% of the estimated fair value of the shares on the date of grant. The exercise price of an ISO granted to an employee who, at the time of grant, owns stock representing more than 10% of the voting power of all classes of stock of the Company (a "10% stockholder") shall be no less than 110% of the estimated fair value of the shares on the date of grant. Options granted under the 2019 Plan have a term of 10 years (or five years if granted to a 10% stockholder) and generally vest over a 4-year period with 1-year cliff vesting.

2015 Equity Incentive Plan

In 2015, the Company established its 2015 Plan which provides for the granting of stock options to employees and consultants of the Company. Options granted under the 2015 Plan may be either ISOs or NSOs.

2019 Employee Stock Purchase Plan

In May 2019, the Company's board of directors adopted and the Company's stockholders approved the 2019 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides eligible employees with the opportunity to acquire an ownership interest in the Company through periodic payroll deductions up to 15% of eligible compensation. The offering period is determined by the Company in its discretion but may not exceed 27 months. The per-share purchase price on the applicable exercise date for an offering period is equal to the lesser of 85% of the fair market value of the common stock at either the first business day or last business day of the offering period, provided that no more than 4,000 shares of common stock may be purchased by any one employee during each offering period. The ESPP is intended to constitute an "employee stock purchase plan" under Section 423(b) of the Internal Revenue Code of 1986, as amended. A total of 195,000 shares of common stock were initially reserved for issuance under the ESPP, subject to an annual increase on January 1 of each year, beginning on January 1, 2020. For the nine months ended September 30, 2020, the Company recorded less than $0.1 million of compensation expense related to participation in the ESPP.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded related to awards granted to employees and non-employees was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 296	$ 227	$ 893	$ 679
General and administrative	685	291	1,670	770
Total stock-based compensation expense	$ 981	$ 518	$ 2,563	$ 1,449

Stock Options

Activity under the Company's 2015 and 2019 Plans is set forth below:

		Outstanding Options		
	Shares available for Grant	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Balance, January 1, 2020	1,036,746	1,962,332	$ 6.03	8.63
Additional shares authorized	813,578	—		
Options granted	(1,205,926)	1,205,926	$ 8.29	
Options exercised	—	(218,724)	$ 4.70	
Options repurchased	10,518	—	$ 1.08	
Options canceled	356,997	(356,997)	$ 6.52	
Balance, September 30, 2020	1,011,913	2,592,537	$ 7.13	8.57
Exercisable as of September 30, 2020		755,278	$ 5.64	7.70
Vested and expected to vest as of September 30, 2020		2,592,537	$ 7.13	8.57

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2020 and September 30, 2019 was $6.00 and $7.20 per share, respectively. The aggregate intrinsic value of options exercised for the nine months ended September 30, 2020 and September 30, 2019 was $1.4 million and $0.7 million, respectively. Intrinsic values are calculated as the difference between the exercise price of the underlying options and the fair value of the common stock on the date of exercise.

As of September 30, 2020 and December 31, 2019, total unrecognized stock-based compensation expense for stock options was $9.0 million and $5.9 million, respectively, which is expected to be recognized over a weighted-average period of 2.67 years and 2.81 years, respectively.

Early Exercise of Stock Options

The terms of the 2015 Plan permit the exercise of options granted under the 2015 Plan prior to vesting, subject to required approvals. The shares so acquired prior to vesting are subject to a lapsing repurchase right in favor of the Company at the original purchase price of such shares, exercisable upon a termination of the holder's service with the Company prior to full vesting. The proceeds are initially recorded in other liabilities from the early exercise of stock options and are reclassified to additional paid-in capital as the Company's repurchase right lapses.

During the nine months ended September 30, 2020 and September 30, 2019, the Company repurchased 10,518 and 14,244 shares of common stock, respectively. As of September 30, 2020 and December 31, 2019, shares that were subject to repurchase were 26,463 and 84,964, respectively. The aggregate exercise price of early exercised shares as of September 30, 2020 and December 31, 2019 was less than $0.1 million and $0.1 million, respectively, which were recorded in other current liabilities and other non-current liabilities.

Black-Scholes Assumptions

The fair values of options were calculated using the assumptions set forth below:

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Expected term	6.1 years	5.4 - 6.1 years	5.5 - 6.1 years	5.4 - 6.1 years
Expected volatility	90.3% - 95.1%	77.2% - 81.6%	84.9% - 95.1%	77.2% - 82.2%
Risk-free interest rate	0.3% - 0.4%	1.4% - 1.9%	0.3% - 1.5%	1.4% - 2.5%
Dividend yield	0%	0%	0%	0%

Expected term. The expected term represents the weighted-average period the stock options are expected to remain outstanding and is based on the options' vesting terms, contractual terms and industry peers, as the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

Expected Volatility. The Company uses an average historical stock price volatility of a peer group of publicly traded companies to be representative of its expected future stock price volatility, as the Company does not have sufficient trading history for its common stock. For purposes of identifying these peer companies, the Company considers the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, the Company measures historical volatility over a period equivalent to the expected term. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate. The risk-free rate assumption is based on U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

Expected Dividend Rate. The Company has not paid and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.

The Company accounts for forfeitures as they occur.

Fair Value of Common Stock

The fair value of the Company's common stock is determined based on its closing market price on the date of grant.

Restricted Stock

Restricted stock activity was as follows:

	Number of Shares Underlying Outstanding Restricted Stock Awards	Weighted Average Grant Date Fair Value
Unvested, December 31, 2019	14,625	$ 0.82
Vested	—	
Unvested, September 30, 2020	14,625	$ 0.82

As of September 30, 2020 and December 31, 2019, 14,625 shares of restricted stock were outstanding with an aggregate purchase price of less than $0.1 million, which is recorded in other non-current liabilities on the balance sheets. The restricted stock vests upon the achievement of pre-defined research milestones. The holder of restricted stock has voting and dividend rights with respect to such shares held without regard to vesting. Shares of restricted stock are subject to a right of repurchase at the original purchase price held by the Company. As the restricted stock was purchased by an employee at a price equal to its fair value at the time of issuance, there was no stock-based compensation expense related to these awards. The total fair value of restricted stock vested during the nine months ended September 30, 2020 and September 30, 2019 was zero and less than $0.1 million in each period.

10. Significant Agreements

GlaxoSmithKline Collaboration, Option and License Agreement

In June 2020, the Company entered into a Collaboration, Option and License Agreement, or the GSK Collaboration Agreement, with an affiliate of GlaxoSmithKline, GLAXOSMITHKLINE INTELLECTUAL PROPERTY (NO. 4), Limited, or GSK, pursuant to which the Company and GSK have entered into a collaboration for its synthetic lethality programs targeting methionine adenosyltransferase 2a, or MAT2A, DNA Polymerase Theta, or Pol Theta or POLQ, and Werner Helicase, or WRN. On July 27, 2020 ("Effective Date"), the Company and GSK received Hart-Scott-Rodino Antitrust Improvements Act clearance, or HSR Clearance, and the GSK Collaboration Agreement became effective.

Pursuant to the GSK Collaboration Agreement, GSK agreed to pay the Company $100.0 million (the "Upfront Payment") within ten business days of the Effective Date of the GSK Collaboration Agreement. On July 31, 2020, the Company received the Upfront Payment.

MAT2A Program

For the MAT2A program, the Company will lead research and development through early clinical development. GSK has an exclusive option to obtain an exclusive license to continue development of and commercialize MAT2A products arising out of the MAT2A program, or the Option, exercisable within a specified time period after the Company delivers to GSK a data package resulting from its conduct of a MAT2A Phase 1 monotherapy clinical trial. At such time of exercise, GSK has agreed to pay the Company an option exercise payment of $50.0 million.

GSK may initiate, or request that the Company initiates, a Phase 1 combination clinical trial for a MAT2A product and GSK's Type I PRMT inhibitor (GSK3368715) product, or the MAT2A Combination Trial, prior to GSK's exercise of the Option. The Company will be responsible for the costs of research and early clinical development activities that the Company conducts for the MAT2A program prior to GSK's exercise of the Option, excluding the costs of conducting the MAT2A Combination Trial. GSK will be solely responsible for costs of the conduct of the MAT2A Combination Trial, except for supply of the MAT2A product therefor, to be provided by the Company at its own cost.

Subject to GSK's exercise of the Option, GSK will lead later stage global clinical development for the MAT2A program, with IDEAYA responsible for 20% and GSK responsible for 80% of further development costs. The cost-sharing percentages will be adjusted based on the actual ratio of U.S. to global profits for MAT2A products, as measured three and six years after global commercial launch thereof.

Subject to GSK's exercise of the Option, the Company will be eligible to receive future development and regulatory milestones of up to $465.0 million, and commercial milestones of up to $475.0 million, with respect to each MAT2A product. Additionally, the Company is entitled to receive 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of MAT2A products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions. The Company will have a right to opt-out of the 50% U.S. net profit share and corresponding development cost share for the MAT2A program, in which case the Company would be eligible to receive tiered royalties on U.S. net sales of MAT2A products by GSK, its affiliates and their sublicensees at the same royalty rates as for global non-U.S. net sales thereafter, with economic adjustments based on the stage of the MAT2A program at the time of opt-out.

Pol Theta Program

Pursuant to the GSK Collaboration Agreement, GSK holds a global, exclusive license to develop and commercialize POLQ products arising out of the POLQ program. GSK and the Company will collaborate on ongoing preclinical research for the POLQ program, and GSK will lead clinical development for the POLQ program. GSK will be responsible for all research and development costs for the POLQ program, including those incurred by the Company.

The Company will be eligible to receive future development and regulatory milestones of up to $485.0 million, with respect to each POLQ product, including as applicable, for multiple POLQ products that target certain alternative protein domains or are based on alternative modalities. Additionally, the Company is eligible to receive up to $475.0 million of commercial milestones with respect to each POLQ product. The Company is also entitled to receive tiered royalties on global net sales of POLQ products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions.

WRN Program

Pursuant to the GSK Collaboration Agreement, GSK holds a global, exclusive license to develop and commercialize WRN products arising out of the WRN program. The Company and GSK will collaborate on ongoing preclinical research for the WRN program, and GSK will lead clinical development for the WRN program, with IDEAYA responsible for 20% and GSK responsible for 80% of such global research and development costs. The cost-sharing percentages will be adjusted based on the actual ratio of U.S. to global profits for WRN products, as measured three and six years after global commercial launch thereof.

The Company will be eligible to receive future development milestones of up to $485.0 million, with respect to each WRN product, including as applicable, for multiple WRN products that are based on alternative modalities. Additionally, the Company will be eligible to receive up to $475.0 million of commercial milestones with respect to each WRN product. The Company will be entitled to receive 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of WRN products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions. The Company will have a right to opt-out of the 50% U.S. net profit share and corresponding research and development cost share for the WRN program, and would be eligible to receive tiered royalties on U.S. net sales of WRN products by GSK, its affiliates and their sublicensees at the same royalty rates as for global non-U.S. net sales thereafter, with economic adjustments based on the stage of the WRN program at the time of opt-out.

General

Under the terms of the GSK Collaboration Agreement, subject to certain exceptions, the Company and GSK will not, directly or through third parties, develop or commercialize other products whose primary and intended mechanism of action is the modulation of WRN, POLQ, or MAT2A (unless GSK does not exercise the Option, in which case such restriction shall cease to apply with respect to MAT2A) for an agreed upon period of time. The Company and GSK will form a joint steering committee, joint development committees, and joint commercialization committees responsible for coordinating all activities under the GSK Collaboration Agreement. Ownership of intellectual property developed under the GSK Collaboration Agreement is allocated between or shared by the parties depending on development and subject matter.

GSK's royalty obligations continue with respect to each country and each product until the later of (i) the date on which such product is no longer covered by certain intellectual property rights in such country and (ii) the 10th anniversary of the first commercial sale of such product in such country.

Each party has the right to sublicense its rights under the GSK Collaboration Agreement subject to certain conditions.

The GSK Collaboration Agreement will continue in effect on a product-by-product and country-by-country basis until the expiration of the obligation to make payments under the GSK Collaboration Agreement with respect to such product in each country, unless earlier terminated by either party pursuant to its terms. Either the Company or GSK may terminate the GSK Collaboration Agreement for the other party's insolvency or certain uncured breaches. The Company may terminate the GSK Collaboration Agreement if GSK or any of its sublicensees or affiliates challenge certain patents of the Company. GSK may terminate the GSK Collaboration Agreement in its entirety or on a target-by-target basis upon 90-day notice to the Company.

Pfizer Clinical Trial Collaboration and Supply Agreement

In March 2020, the Company entered into a clinical trial collaboration and supply agreement with Pfizer Inc., or the Supply Agreement, which was subsequently amended in September 2020. Pursuant to the Supply Agreement, Pfizer supplies the Company with their MEK inhibitor, binimetinib, and cMET inhibitor, crizotinib, to evaluate the combination in patients with tumors harboring activating GNAQ or GNA11 hotspot mutations. Under the Supply Agreement, the Company will sponsor a Phase 1/2 clinical trial for its product candidate, IDE196, and Pfizer will supply the Company with binimetinib and crizotinib for use in the clinical trial at no cost to the Company. The Supply Agreement provides that the Company and Pfizer will jointly own clinical data generated from the clinical trial.

11. Revenue Recognition

The Company recognizes revenue in accordance with ASC 606 for the GSK Collaboration Agreement (see No. 10, Significant Agreements).

Contract balances

As of September 30, 2020, the company had $91.0 million of contract liabilities, and no balance of accounts receivable or contract asset related to the GSK Collaboration Agreement.

The timing of revenue recognition, billings, and cash collections results in accounts receivable, contract assets, and contract liabilities on the balance sheets. Subsequent to each quarter end, when the Company and GSK finalizes the reimbursable program costs, the Company recognizes accounts receivable, which are derecognized upon reimbursement. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Contract liabilities are recognized as revenue after control of the products or services is transferred to the customer and all revenue recognition criteria have been met.

Performance obligations

The Company has identified the following six performance obligations associated with the GSK Collaboration Agreement:

(i) Preclinical and Phase 1 Monotherapy clinical research and development services under the MAT2A program ("MAT2A R&D Services")

(ii) Preclinical research services and the related license to IDEAYA-owned technology under the Pol Theta program ("Pol Theta R&D Services")

(iii) Preclinical research services and the related license to IDEAYA-owned technology under the WRN program ("WRN R&D Services")

(iv) Material right associated with the option to license IDEAYA-owned technology under the MAT2A program (defined as the "Option" in Note 10)

(v) Material right associated with the option to license to IDEAYA-owned technology under the MAT2A program to the extent necessary for preclinical activities in preparation for the MAT2A Combination Trial ("Preclinical MAT2A License")

(vi) Material right associated with the supply of MAT2A product for the MAT2A Combination Trial ("MAT2A Supply")

The Company will recognize revenue related to amounts allocated to the MAT2A R&D services as the underlying services are performed over the period through the delivery of the data package, which will be generated from its conduct of the MAT2A Phase 1 monotherapy clinical trial. The Company uses its internal research and development capability and may also engage third-party clinical research organizations, or CROs, in transferring the MAT2A R&D services, for which the Company acts as a principal.

With respect to the Pol Theta and WRN programs, the Company identified two promises: (1) granting of the license to develop and commercialize Pol Theta and WRN products, respectively, and (2) the preclinical research services. The Company has determined that these two promises are not distinct within the context of the contract. As of the effective date of the GSK Collaboration Agreement, both programs were at an early stage, and the Company was yet to identify any development candidate for either program, which will require the completion of certain preclinical studies. After the Company and GSK identify a development candidate, a series of IND-enabling studies will be conducted before an Investigational New Drug application is submitted to the FDA. Due to the early stage of development, the Company's preclinical research services are expected to transform the underlying technology and significantly modify or customize the license. Therefore, the two promises are not distinct from each other and are accounted for as a single performance obligation for each of the Pol Theta and WRN programs, respectively. The Company will recognize revenue related to amounts allocated to the Pol Theta R&D Services and WRN R&D Services as the underlying services are performed over the period through the completion of the Pol Theta and WRN preclinical research programs, respectively. Within 90 days from the end of each calendar quarter, GSK will reimburse the Pol Theta program costs incurred by the Company. Within 75 days from the end of each calendar quarter, the Company and GSK will determine the amounts of WRN program costs incurred by both parties and the net amount owed by GSK to the Company or by the Company to GSK, which will be paid within 75 days from such determination by a reimbursing party. The Company uses its internal research capability and may also engage third-party clinical research organizations, or CROs, in transferring the Pol Theta R&D services and WRN R&D services, for which the Company acts as a principal.

Upon exercise of the Option, GSK will obtain the license to develop and commercialize MAT2A products. The Company has concluded that this Option results in a material right as the option exercise fee contains a discount that GSK would not have otherwise received. The Company has determined the nature of the license to develop and commercialize MAT2A products to be functional. After exercise of the Option, the Company will recognize revenue, when it makes the underlying MAT2A technology available to GSK, which will immediately be able to use and benefit from its right to use the intellectual property.

The Company has identified two additional customer options under the MAT2A program, both of which have been determined a material right. GSK may elect to conduct certain preclinical activities in preparation for the MAT2A Combination Trial and may elect to exercise the option to license to MAT2A technology. GSK may be able to use and exploit the license to the extent necessary for GSK's performance of such preclinical activities. The Company will not receive any consideration for providing such license and has concluded that this license option results in a material right as it involves a discount that GSK would not have otherwise received. The Company has determined the nature of such license to MAT2A technology to be functional. As of September 30, 2020, GSK has exercised the Preclinical MAT2A License, and the Company has made the underlying MAT2A technology available to GSK, which is immediately able to use and benefit from its right to use the intellectual property. Accordingly, the Company recognized revenue from the Preclinical MAT2A License in the quarter ended September 30, 2020.

If GSK elects to conduct the MAT2A Combination Trial, the Company will supply MAT2A product to be used for the MAT2A Combination Trial at its own cost. The Company has concluded that this supply option results in a material right as it involves a discount that GSK would not have otherwise received. The Company will recognize revenue, as it transfers the control of the MAT2A product to GSK. The Company has not supplied MAT2A product as of September 30, 2020.

Transaction price allocated to the remaining performance obligations

At inception of the GSK Collaboration Agreement, the Company determined that the transaction price was $108.5 million, including the Upfront Payment, and the estimated reimbursable program costs. The remaining aggregated performance obligations as of September 30, 2020 were $96.6 million, $48.7 million of which is expected to be satisfied over the next 12 months.

The Company applies the sales-based royalty exception to the commercial milestones and tiered royalties for all programs because GSK would ascribe significantly more value to the license than to the other goods or services to which the commercial milestones and tiered royalties relate. The Company will be entitled to receive the commercial milestones either when the first commercial sale occurs, or when the predefined net sales in a calendar year are achieved, upon which the variability will be resolved. Also, the Company will be entitled to receive the tiered royalties during a calendar year when global net sales of each product occur, upon which the variability will be resolved.

Significant judgements

In applying ASC 606 to the GSK Collaboration Agreement, the Company made the following judgments that significantly affect the timing and amount of revenue recognition:

1. *Determination of the transaction price, including whether any variable consideration is included at inception of the contract*

The transaction price is the amount of consideration that the Company expects to be entitled to in exchange for transferring promised goods or services to the customer. The transaction price must be determined at inception of a contract and may include amounts of variable consideration. However, there is a constraint on inclusion of variable consideration in the transaction price, if there is uncertainty at inception of the contract as to whether such consideration will be recognized in the future.

The decision as to whether or not it is probable that a significant reversal of revenue will occur in the future, depends on the likelihood and magnitude of the reversal and is highly susceptible to factors outside the Company's influence (for example, the Company cannot determine the outcome of clinical trials; the Company cannot determine if or when the counterparty will initiate or complete clinical trials; and the Company cannot determine if or when an regulatory agency provides any approval). In addition, the uncertainty is not expected to be resolved for a long period and finally, the Company has limited experience in the field. Therefore, at inception of the GSK Collaboration Agreement, development and regulatory milestones were fully constrained and were not included in the transaction price based on the factors noted above.

The Company constrains estimates of other variable consideration, such as reimbursable program costs, to amounts that are not expected to result in a significant revenue reversal in the future. The Company re-evaluates the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

2. Determination of the estimate of the standalone selling price of performance obligations

In order to recognize revenue under ASC 606, for contracts for which more than one distinct performance obligation has been identified, the Company must allocate the transaction price to the performance obligations based upon their standalone selling prices. The best evidence of standalone selling price is an observable price of a good or service when sold separately by an entity in similar circumstances to similar customers. If such evidence is not available, standalone selling price should be estimated so that the amount that is allocated to each performance obligation equals the amount that the entity expects to receive for transferring goods or services. The Company has identified more than one performance obligation in the GSK Collaboration Agreement. Since evidence based on observable prices is not available for the performance obligations, the Company considered market conditions and entity-specific factors, including those contemplated in negotiating the agreements, as well as certain internally developed estimates.

The Company determined the estimate of standalone selling price of the MAT2A R&D Services, Pol Theta R&D Services, and WRN R&D Services by using the expected costs of satisfying the performance obligation, adjusted for probabilities of technical success where appropriate. The Company determined the estimate of standalone selling price of the Option by using risk-adjusted net present value analysis. Finally, the Company determined the estimate of standalone selling price of the Preclinical MAT2A License and MAT2A Supply by using the expected costs of satisfying the performance obligation.

3. Determination of the method of allocation of the transaction price to the distinct performance obligations

At inception of the GSK Collaboration Agreement, the Company allocated the transaction price among the six performance obligations based on their relative selling prices, determined as described above.

4. Determination of the timing of satisfaction of performance obligations

The Company recognizes revenue from the MAT2A R&D Services, Pol Theta R&D Services and WRN R&D Services over time, as GSK simultaneously receives and consumes the benefits provided by the Company’s performance as the Company performs. The Company measures its progress toward complete satisfaction of the MAT2A R&D Services, Pol Theta R&D Services and WRN R&D Services based on the costs incurred as a percentage of the estimated total costs to be incurred to complete the performance obligations. As the Company performs, it shares the results of research and development studies with GSK through the joint development committee. Accordingly, the cost incurred method faithfully depicts the Company’s performance of the MAT2A R&D Services, Pol Theta R&D Services and WRN R&D Services.

The license to IDEAYA-owned technology under the MAT2A program underlying the Option and Preclinical MAT2A License is functional in nature. Upon the exercise of the material right associated with the option to license to IDEAYA-owned technology under the MAT2A program, the Company will recognize revenue upon the later of transfer of the underlying technology to GSK and the beginning of the period during which GSK is able to use and benefit from its right to use the underlying technology.

After the exercise of the material right associated with the supply of MAT2A product for the MAT2A Combination Trial, the Company recognize revenue as it transfers the control of MAT2A product to GSK.

12. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss attributable to common stockholders	$ (4,926)	$ (10,969)	$ (29,360)	$ (31,194)
Denominator:				
Weighted-average shares outstanding	28,447,329	20,307,383	23,305,249	10,087,459
Less: weighted-average unvested restricted shares and shares subject to repurchase	(50,659)	(149,160)	(70,031)	(191,885)
Weighted-average shares used in computing net loss per share attributable to common stock, basic and diluted	28,396,670	20,158,223	23,235,218	9,895,574
Net loss per share attributable to common stockholders, basic and diluted	$ (0.17)	$ (0.54)	$ (1.26)	$ (3.15)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	As of September 30,	
	2020	2019
Options to purchase common stock	2,592,537	1,921,259
Unvested restricted stock awards	14,625	14,899
Unvested early exercised common stock options	26,463	116,306
Total	2,633,625	2,052,464

As of September 30, 2020, the Company has contributions from plan participants of $0.2 million under the ESPP, which if converted, would be equivalent to 22,236 shares based on 85% of the stock price at the beginning of the offering period.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described, in or implied, by these forward-looking statements. Please also see the section of this Quarterly Report on Form 10-Q titled "Forward-Looking Statements."

Overview

We are an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. Our approach integrates small molecule drug discovery with extensive capabilities in identifying and validating translational biomarkers to develop targeted therapies for select patient populations most likely to benefit. Our small molecule drug discovery expertise includes discovery and development of small molecule inhibitors and protein degrader modalities. We are applying these capabilities to develop a robust pipeline in precision medicine oncology, with a research focus in synthetic lethality – which represents an emerging class of precision medicine targets.

IDE397 – MAT2A Inhibitor Development Candidate

Our lead synthetic lethality research program targets methionine adenosyltransferase 2a, or MAT2A, for solid tumors with MTAP deletions, a patient population estimated to represent approximately 15% of solid tumors.

Our MAT2A inhibitor development candidate is designated as IDE397. Our preclinical activities continue to support IDE397 as a development candidate and a potential clinical candidate.

We are evaluating the efficacy of monotherapy IDE397 in over forty solid tumor patient derived xenograft, or PDX, models with homozygous MTAP deletions. Preliminary results show *in vivo* efficacy in multiple MTAP-null xenograft models demonstrating tumor growth inhibition when MAT2A is pharmacologically inhibited with IDE397 as monotherapy, including in non-small cell lung cancer.

We have completed the in-life phase of our ongoing good laboratory practice, or GLP, compliant toxicology studies with IDE397 in multiple species.

Subject to satisfactory completion of GLP toxicology studies and completion of chemistry, manufacturing and control, or CMC, certification requirements, we are targeting to submit an investigational new drug application, or IND, to the FDA for IDE397 in December 2020. Subject to effectiveness of the IND, we anticipate initiating a Phase 1 clinical trial for clinical evaluation of IDE397 as monotherapy in the first half of 2021.

Preclinical combination tolerability and efficacy studies are ongoing with IDE397 and GSK3368715, GSK's Phase 1 Type 1 PRMT inhibitor, including in multiple MTAP-null *in vivo* efficacy models.

We plan to lead research and development of IDE397 through early clinical development, in collaboration with GlaxoSmithKline pursuant to the Collaboration, Option and License Agreement, or the GSK Collaboration Agreement, with an affiliate of GlaxoSmithKline, GLAXOSMITHKLINE INTELLECTUAL PROPERTY (NO. 4), Limited, or GSK.

PARG

We are advancing our preclinical research for an inhibitor of poly (ADP-ribose) glycohydrolase, or PARG, for patients having tumors with BRCA2 mutations and potentially other genetic and/or molecular signatures.

One of our PARG inhibitor compounds, designated as IDB-PARG, has demonstrated dose-dependent *in vivo* efficacy as monotherapy with tumor regression or stasis in multiple PDX models.

We are continuing to evaluate the efficacy of IDB-PARG as monotherapy across a panel of additional solid tumor PDX models with specific genetic alterations.

We entered into a strategic collaboration with the Broad Institute of MIT and Harvard focused on synthetic lethality target and biomarker discovery. Among other objectives, our collaboration with the Broad Institute will evaluate paralog CRISPR knockdown in selected cell lines in conjunction with pharmacological inhibition of PARG to inform patient selection and combination strategies in ovarian and breast cancer.

Subject to further preclinical studies, we are targeting to identify a PARG inhibitor development candidate in 2021.

Werner Helicase

We are also continuing to advance our preclinical research in collaboration with GSK for an inhibitor targeting Werner Helicase, or WRN, for patients having tumors with high microsatellite instability, or MSI. We have observed dose-dependent cellular viability effect and a dose-dependent cellular pharmacodynamic, or PD, response in multiple endogenous MSI high cell lines.

For this program, we plan to continue further development in collaboration with GSK pursuant to the GSK Collaboration Agreement.

Pol Theta

We are progressing our program targeting DNA Polymerase Theta, or Pol Theta or POLQ, in collaboration with GSK for patients having solid tumors with BRCA or other homologous recombination deficiency, or HRD, mutations. We have shown combination activity with multiple PARP inhibitors, including niraparib. We have demonstrated synergistic *in vivo* efficacy of a Pol-theta inhibitor with niraparib: the combination of our Pol Theta inhibitor with niraparib enhanced the activity of niraparib in the DLD1 BRCA2-/- xenograft model. Tumor regressions were observed for all animals in the study which were administered the combination.

We plan to continue further development of our POLQ program, including both protein degraders and small molecule inhibitors in collaboration with GSK pursuant to the GSK Collaboration Agreement, and are targeting selecting a development candidate for a Pol Theta small molecule inhibitor in 2021.

DNA Damage Target

We have initiated early preclinical research programs to identify small molecule inhibitors for multiple distinct DNA Damage Targets, or DDTs, for patients with solid tumors characterized by a proprietary biomarker or a gene signature.

Synthetic Lethality Target and Biomarker Discovery Platform

Synthetic lethality continues to be our core research focus. We have invested significantly and continue to invest in capabilities for identification and validation of new synthetic lethality targets. For targets of interest, we advance our research to discover therapeutic drugs and relevant biomarkers.

Our synthetic lethality research platform integrates a broad set of computational and functional capabilities. These capabilities collectively reflect the convergence of advancements in biology, molecular biology, chemistry and information technologies. For example, molecular biology approaches such as gene knockdown using siRNA, gene editing using CRISPR, quantitative DNA/RNA analysis, protein expression profiling and genomic sequencing can be applied across broad cell lines to create substantial data sets. Data analytics and computational approaches are used to mine such data sets to identify novel targets and biomarker hypotheses. These hypotheses are experimentally validated by developing and applying relevant biological assays.

We have established a comprehensive platform to computationally and empirically identify high value synthetic lethal pairs in defined patient populations. This platform integrates across parallel data sets, each including orthogonal content based on particular screening efforts. These screens include evaluation of curated, genetically defined and preselected model cell sets indicative of targeted patient populations. Our platform includes a proprietary library and data set resulting from our DECIPHER™ Dual CRISPR Synthetic Lethality library constructed in collaboration with University of California, San Diego. The platform will also include data from our recently announced proprietary PAGEO™, or Paralogous Gene Evaluation in Ovarian cancer, library being developed in collaboration with the Broad Institute utilizing the Sellers laboratory CRISPR paralog screening platform to evaluate functionally redundant paralogous genes across ovarian cancer subtypes. Additionally, we are members of the DepMap (Cancer Dependency Map) consortium led by the Broad Institute, through which we have access to a comprehensive data set of genome-wide cell-based screens, including isogenic screens, conducted by the Broad Institute and other contributing institutes, including pre-publication access to new data releases. As a further component of our synthetic lethality platform, we are conducting computational data mining and analysis of relevant public databases, such as The Cancer Genome Atlas, or TCGA, cBioPortal, and Cancer Cell Line Encyclopedia, or CCLE, among others. Such computational approaches include our proprietary algorithms which enable us to determine synthetic lethality targets and biomarkers enabling patient stratification.

We have established internal bioinformatics capabilities, which are supplemented by external resources. We are applying these capabilities and resources to integrate using proprietary algorithms and unsupervised machine learning across each of the orthogonal data sets in our platform. These integrated, comprehensive analysis efforts allow us to determine synthetic lethality target / biomarker pairs with the strongest signals across the data sets. Potential therapeutic targets are ranked based on several factors, including the strength of the synthetic lethal interaction, potential drugability, potential clinical development path, and potential market opportunity. The most promising therapeutic targets are validated empirically.

DECIPHER™ Dual CRISPER Synthetic Lethality Library – UCSD

We have constructed our DECIPHER Dual CRISPR library for synthetic lethality target and biomarker discovery in collaboration with the University of California, San Diego, and bioinformatics analysis and validation are ongoing. The DECIPHER 1.0 library is focused on DNA Damage Repair targets across various tumor suppressor genes and oncogenes of interest that were selected based on their known prevalence and role in solid tumors, enabling evaluation of approximately 50,000 independent gene knockout combinations of DDR pathway related drug targets across known tumor suppressor genes.

PAGEO™ Paralogous Gene Evaluation in Ovarian Cancer and Dep Map Consortium – Broad Institute

On October 21, 2020, we entered into a strategic collaboration with the Broad Institute of MIT and Harvard focused on synthetic lethality target and biomarker discovery. This collaboration will use the large-scale CRISPR paralog screening platform developed at the laboratory of William R. Sellers, M.D., Core Institute Member, Broad Institute, to evaluate functionally redundant paralogous genes across ovarian cancer subtypes and to generate novel target and biomarker hypotheses. Dr. Sellers, who also serves on our Scientific Advisory Board, is the principal investigator for the strategic collaboration. We have also become a member of the Broad DepMap (Cancer Dependency Map) consortium led by the Broad Institute to further enhance our efforts in bioinformatics and cell-based screening for synthetic lethality target and biomarker discovery and validation.

We are also continuing to invest in our capabilities to advance our research on newly identified synthetic lethality targets of interest, including to enable discovery of therapeutic drugs and relevant biomarkers. These investments include both additional research personnel and capital investments, which will enhance our capabilities broadly, including in target validation, biological assay development, protein synthesis, structural biology, computational chemistry, and analytical chemistry, among other core functional areas.

Collaboration, Option and License Agreement with GSK for Synthetic Lethality Programs

On June 15, 2020, we entered into the GSK Collaboration Agreement, with GSK, pursuant to which we and GSK have entered into a strategic partnership and collaboration for our synthetic lethality programs targeting MAT2A, Pol Theta and Werner Helicase.

On July 27, 2020, or the Effective Date, the GSK Collaboration Agreement became effective upon the parties' receipt of Hart-Scott-Rodino Antitrust Improvements Act clearance, or HSR Clearance. We received from GSK an up-front payment of $100.0 million in cash following the Effective Date.

GSK Collaboration – MAT2A Program

For the MAT2A program, we will continue to lead research and development through early clinical development. GSK has an exclusive option to obtain an exclusive license to continue development of and commercialize MAT2A products arising out of the MAT2A program, or the Option, exercisable within a specified time period after we deliver to GSK a data package resulting from our conduct of a MAT2A Phase 1 monotherapy clinical trial. GSK's exercise of the Option may be subject to HSR Clearance therefor at such time of exercise, and following exercise and HSR Clearance, GSK has agreed to pay us an option exercise payment of $50.0 million.

GSK may initiate, or request that we initiate, a Phase 1 combination clinical trial for a MAT2A product and GSK's Type I PRMT inhibitor (GSK3368715) product, or the MAT2A Combination Trial, prior to GSK's exercise of the Option. We will be responsible for the costs of research and early clinical development activities that we conduct for the MAT2A program prior to GSK's exercise of the Option (including during any interim waiting period for HSR Clearance for such Option exercise, if applicable), excluding the costs of conducting the MAT2A Combination Trial. GSK will be solely responsible for costs of the conduct of the MAT2A Combination Trial, except for supply of the MAT2A product therefor, to be provided by us at our own cost.

Subject to GSK's exercise of the Option (and HSR Clearance thereof, if applicable), GSK will lead later stage global clinical development for the MAT2A program, with IDEAYA responsible for 20% and GSK responsible for 80% of further development costs. The cost-sharing percentages will be adjusted based on the actual ratio of U.S. to global profits for MAT2A products, as measured three and six years after global commercial launch thereof.

Subject to GSK's exercise of the Option (and HSR Clearance thereof, if applicable), we will be eligible to receive future development and regulatory milestones of up to $465.0 million, and commercial milestones of up to $475.0 million, with respect to each MAT2A product. Additionally, we are entitled to receive 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of MAT2A products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions. We have a right to opt-out of the 50% U.S. net profit share and corresponding development cost share for the MAT2A program, in which case we would be eligible to receive tiered royalties on U.S. net sales of MAT2A products by GSK, its affiliates and their sublicensees at the same royalty rates as for global non-U.S. net sales thereafter, with economic adjustments based on the stage of the MAT2A program at the time of opt-out.

GSK Collaboration - Pol Theta Program

Pursuant to the GSK Collaboration Agreement, GSK holds a global, exclusive license to develop and commercialize POLQ products arising out of the POLQ program. GSK and we will collaborate on ongoing preclinical research for the POLQ program, and GSK will lead clinical development for the POLQ program. GSK will be responsible for all research and development costs for the POLQ program, including those incurred by us.

We will be eligible to receive future development and regulatory milestones of up to $485.0 million, with respect to each POLQ product, including as applicable, for multiple POLQ products that target certain alternative protein domains or are based on alternative modalities. Additionally, we are eligible to receive up to $475.0 million of commercial milestones with respect to each POLQ product. We are also entitled to receive tiered royalties on global net sales of POLQ products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions.

We believe there are potential synergies to evaluate a combination between our Pol Theta program and GSK's approved PARP inhibitor, Zejula™, targeting the BRCA and HRD patient population.

GSK Collaboration - Werner Helicase Program

Pursuant to the GSK Collaboration Agreement, GSK holds a global, exclusive license to develop and commercialize WRN products arising out of the WRN program. We and GSK will collaborate on ongoing preclinical research for the WRN program, and GSK will lead clinical development for the WRN program, with IDEAYA responsible for 20% and GSK responsible for 80% of such global research and development costs. The cost-sharing percentages will be adjusted based on the actual ratio of U.S. to global profits for WRN products, as measured three and six years after global commercial launch thereof.

We will be eligible to receive future development milestones of up to $485.0 million, with respect to each WRN product, including as applicable, for multiple WRN products that are based on alternative modalities. Additionally, we will be eligible to receive up to $475.0 million of commercial milestones with respect to each WRN product. We will be entitled to receive 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of WRN products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions. We will have a right to opt-out of the 50% U.S. net profit share and corresponding research and development cost share for the WRN program, and would be eligible to receive tiered royalties on U.S. net sales of WRN products by GSK, its affiliates and their sublicensees at the same royalty rates as for global non-U.S. net sales thereafter, with economic adjustments based on the stage of the WRN program at the time of opt-out.

GSK Collaboration - General

Under the terms of the GSK Collaboration Agreement, subject to certain exceptions, we and GSK will not, directly or through third parties, develop or commercialize other products whose primary and intended mechanism of action is the modulation of WRN, POLQ, or MAT2A (unless GSK does not exercise the Option or HSR Clearance does not occur with respect thereto, in which case such restriction shall cease to apply with respect to MAT2A) for an agreed upon period of time. We and GSK will form a joint steering committee, joint development committees, and joint commercialization committees responsible for coordinating all activities under the GSK Collaboration Agreement.

GSK’s royalty obligations continue with respect to each country and each product until the later of (i) the date on which such product is no longer covered by certain intellectual property rights in such country and (ii) the 10th anniversary of the first commercial sale of such product in such country.

Each party has the right to sublicense its rights under the GSK Collaboration Agreement subject to certain conditions.

The GSK Collaboration Agreement will continue in effect on a product-by-product and country-by-country basis until the expiration of the obligation to make payments under the GSK Collaboration Agreement with respect to such product in each country, unless earlier terminated by either party pursuant to its terms. Either we or GSK may terminate the GSK Collaboration Agreement for the other party’s insolvency or certain uncured breaches. We may terminate the GSK Collaboration Agreement if GSK or any of its sublicensees or affiliates challenge certain patents of the Company. GSK may terminate the GSK Collaboration Agreement in its entirety or on a target-by-target basis upon 90-day notice to us.

The GSK Collaboration Agreement contains various representations, warranties, covenants, dispute resolution mechanisms, indemnities and other provisions generally customary for transactions of this nature.

IDE196 - PKC Inhibitor Clinical Candidate

We continue to execute on our ongoing Phase 1/2 clinical trial and preclinical research activities for our clinical candidate IDE196, a protein kinase C, or PKC, inhibitor for genetically-defined cancers having activating GNAQ or GNA11 hotspot mutations, including in metastatic uveal melanoma, or MUM, skin melanoma and other solid tumors.

Our clinical trial strategy is to pursue IDE196 combination therapies in MUM, including with binimetinib, a MEK inhibitor, and independently with crizotinib, a cMET inhibitor, each pursuant to our Clinical Trial Collaboration and Supply Agreement, or Pfizer Agreement, with Pfizer. We have formed a joint development committee with Pfizer responsible for coordinating all regulatory and other activities under the Pfizer Agreement, including for both the IDE196/binimetinib combination study and IDE196/crizotinib combination study. If the clinical data from either or both of these combination studies is positive, we plan to enter into good faith negotiations with Pfizer to determine a regulatory submission strategy.

We are continuing to evaluate IDE196 as monotherapy in non-MUM cancers, including in skin melanoma, where we recently announced meeting the clinical protocol criteria for an expansion cohort, based on observing one confirmed partial response in an initial four evaluable patients.

IDE196 / Binimetinib Combination Therapy

On June 26, 2020, we initiated a combination arm of our Phase 1/2 clinical trial to evaluate IDE196 in combination with binimetinib in patients having tumors harboring activating GNAQ or GNA11 hotspot mutations. An initial dose escalation portion of this arm of the clinical trial is evaluating the safety and efficacy of IDE196 in combination with binimetinib at various dose combinations, initially in patients with metastatic uveal melanoma, or MUM. Following our evaluation of tolerability and preliminary efficacy from the IDE196 / binimetinib combination arm of the clinical trial in MUM, we may also evaluate IDE196 / binimetinib combination therapy in patients having other solid tumors with activating GNAQ/11 hotspot mutations outside of uveal melanoma, such as skin melanoma.

The IDE196 / binimetinib combination arm of our Phase 1/2 clinical trial is supported through the Pfizer Agreement, pursuant to which Pfizer supplies us with their MEK inhibitor, binimetinib. We have established a joint development committee with Pfizer to facilitate combination arm drug supply, trial initiation and ongoing development.

We are continuing patient enrollment into the IDE196 / binimetinib combination arm under the clinical trial collaboration and supply agreement with Pfizer and are targeting combination expansion in the first quarter of 2021. We anticipate interim data from the IDE196 / binimetinib combination therapy Phase 1/2 portion of the clinical trial in MUM patients in 2021.

IDE196 / Crizotinib Combination Therapy

On September 23, 2020, we expanded the scope of our Pfizer Agreement to evaluate IDE196 and crizotinib as a combination therapy in patients having tumors harboring activating GNAQ or GNA11 hotspot mutations.

We identified cMET as a potential biomarker and a cMET inhibitor as potential combination agent though our ongoing translational research. We observed preclinical synergies in cellular models, and a retrospective analysis of human clinical samples from the Novartis Phase 1 clinical trial also independently supported cMET expression / activation as potential biomarker / combo agent.

We are the sponsor of this arm of the clinical trial and are targeting initiation in late 2020 to early 2021 to evaluate the combination of IDE196 and crizotinib. An initial dose escalation portion of this arm of the clinical trial will be evaluating the safety and efficacy of IDE196 in combination with crizotinib at various dose combinations, initially in patients with metastatic uveal melanoma, or MUM. Following our evaluation of tolerability and preliminary efficacy from the IDE196 / crizotinib combination arm of the clinical trial in MUM, we may also evaluate IDE196 / crizotinib combination therapy in patients having other solid tumors with activating GNAQ/11 hotspot mutations outside of uveal melanoma, such as skin melanoma.

Pursuant to the Pfizer Agreement, Pfizer will supply us with their cMET inhibitor, crizotinib. We have established a joint development committee with Pfizer to facilitate combination arm drug supply, trial initiation and ongoing development.

IDE196 Monotherapy

Our ongoing monotherapy arm of the Phase 1/2 clinical trial was initiated in June 2019 to evaluate IDE196 in solid tumors harboring GNAQ or GNA11 hotspot mutations in a basket trial design. We have completed enrollment in the monotherapy arm of the Phase 1/2 clinical trial in MUM. We are also enrolling other, non-MUM solid tumors harboring GNAQ or GNA11 hotspot mutations, such as skin melanoma.

In the Phase 2 basket arm evaluating IDE196 as monotherapy in non-MUM solid tumors harboring GNAQ or GNA11 hotspot mutations (GNAQ/11), the clinical protocol criteria have been met for cohort expansion in cutaneous melanoma, or skin melanoma. We are actively enrolling for this Phase 2 cohort expansion in skin melanoma. Of 4 evaluable skin melanoma patients harboring GNAQ/11 hotspot mutations (excluding 1 non-evaluable) as of August 1, 2020, a 100% Disease Control Rate was observed, and one confirmed partial response (cPR) was determined by RESIST, or Response Evaluation Criteria in Solid Tumors, 1.1 guidelines, satisfying the protocol requirement of at least one RECIST response in the first Stage 1 cohort (n=9) in order to expand into a second Stage 2 cohort (n=15). Following satisfaction of the clinical protocol criteria, we can enroll an additional 15 skin melanoma patients harboring GNAQ/11 mutations into the Stage 2 cohort expansion, for a total planned enrollment of 24 patients in the skin melanoma cohort.

As of November 1, 2020, we have enrolled a total of seven patients with solid tumors other than MUM, including six patients with skin melanoma, into the Phase 2 monotherapy basket arm.

We have added and are continuing to access potential additional clinical trial sites to supplement enrollment into the Phase 2 basket arm of the IDE196 clinical trial. We have established a relationship with Tempus and with CARIS, in each case through which we are accessing their network of clinical trial sites into which we can enroll qualifying patients having tumors harboring GNAQ/11 hotspot mutations.

We anticipate disclosing interim data from the monotherapy arm of our ongoing IDE196-001 Phase 1/2 basket trial in 2021.

IDE196 was initially developed by Novartis, and we obtained an exclusive, worldwide license to IDE196 from Novartis in September 2018. Pursuant to our license agreement with Novartis, except for Novartis' ongoing Phase 1 clinical trial, we control all future clinical development, and all commercial rights to IDE196, and may rely on and incorporate data previously submitted to the FDA by Novartis into our own regulatory submissions. Novartis has completed enrollment in a Phase 1 clinical trial it is conducting to evaluate IDE196 in metastatic uveal melanoma. Phase 1 monotherapy data from Novartis was presented at the American Association for Cancer Research, or AACR, in April 2019.

Regulatory / Potentially Registration-Enabling Clinical Trial

In an end of Phase 1 meeting with the FDA in the fourth quarter of 2019, the FDA indicated that our proposed single-arm Phase 2 portion of the IDE196 001 Phase 1/2 clinical trial may be adequate to support a new drug application, or NDA, seeking Accelerated Approval for IDE196 monotherapy in MUM. The FDA indicated that such a single-arm, potentially registration enabling part of the Phase 1/2 clinical trial could target enrollment of 60 evaluable MUM patients with the primary endpoint of overall response rate, or ORR, as determined by blinded independent central review, or BICR, supported by BICR determined duration of response, or DOR, as a secondary endpoint.

We initiated 13-week good laboratory practice-, or GLP-, compliant toxicology studies in two species in November 2019, in support of an FDA requirement that results of these studies be submitted prior to enrollment of more than approximately 50 patients in the potentially registrational arm that will support a marketing application. We have completed the 13-week preclinical toxicology studies of IDE196 in two species.

We plan to evaluate clinical tolerability and efficacy data from each of the ongoing IDE196 monotherapy Phase 1 portion of the clinical trial in MUM patients and the IDE196 combination therapy Phase 1/2 portions of the clinical trial in MUM patients, as well as potential strategic partnering of the IDE196 program, prior to initiation of a potentially registrational clinical trial in MUM. We will provide updated guidance on timing for a potential NDA submission for IDE196 in MUM after making such decision on a potential registrational pathway in MUM.

Other Potential Indications

We are continuing our preclinical evaluation of IDE196 in Sturge-Weber Syndrome, or SWS, a rare neurocutaneous disorder characterized by capillary malformations and associated with mutations in GNAQ. Our preclinical evaluation will include potential feasibility for pediatric use.

Impact of COVID-19 Pandemic on IDE-001 Phase 1/2 Clinical Trial and IDE196 Preclinical Research

We continue to monitor the COVID-19 pandemic and its potential impact on the ongoing IDE196 clinical program. GNAQ/11 patients enrolled in the ongoing Phase 1/2 clinical trial and sites affected by COVID-19 restrictions are adapting to logistical constraints on activities, such as travel and site visits. For example, patients are continuing on IDE196 therapy, which is an oral drug and is being shipped to and self-administered by patients at home. Patients are being monitored through a combination of telemedicine visits and local visits. COVID-19 infection rates have increased recently in several states in which our clinical trial sites are located. As such, ongoing monitoring of enrolled patients, including obtaining patient computed tomography, or CT, scans, may be impacted; the specific impact is currently uncertain.

Additionally, enrollment into the Phase 2 expansion arm for IDE196 as a monotherapy in non-MUM solid tumors having GNAQ or GNA11 hotspot mutations may be delayed by circumstances resulting from the COVID-19 pandemic, including for example, as a result of recent increases in COVID-19 infection rates in several states in which our clinical trial sites are located, and by clinical site-specific policies and practices related to COVID-19. The specific impact on enrollment into the Phase 2 expansion of the monotherapy arm for non-MUM solid tumors having GNAQ or GNA11 hotspot mutations is currently uncertain.

Enrollment into the combination arm evaluating IDE196 and binimetinib and/or the combination arm of IDE196 and crizotinib, in each case as combination therapy in MUM and non-MUM solid tumors having GNAQ or GNA11 hotspot mutations, may be delayed by circumstances resulting from the COVID-19 pandemic, including for example, by clinical site-specific policies and practices related to COVID-19. The specific impact on enrollment into this combination arm of the Phase 1/2 clinical trial is currently uncertain.

We plan to continue to use third-party service providers, including clinical research organizations, or CROs, and clinical manufacturing organizations, or CMOs, to carry out our preclinical and clinical development and manufacture and supply of our preclinical and clinical materials to be used during the development of our product candidates. To date, the COVID-19 pandemic has not materially affected our supply chain or development schedule, but further escalation of the health crisis has the potential to cause delays in our supply chain and manufacturing operations, which could materially adversely impact our business.

Clinical Trial Collaboration and Supply Agreement for IDE196 Program

On March 11, 2020, we entered into the Pfizer Agreement with Pfizer Inc., pursuant to which Pfizer will supply us with their MEK inhibitor, binimetinib, to evaluate the combination in patients with tumors harboring activating GNAQ or GNA11 hotspot mutations.

On September 23, 2020, we expanded the scope of our clinical trial collaboration and supply agreement with Pfizer, pursuant to which Pfizer will supply us with their cMET inhibitor, crizotinib to evaluate IDE196 and crizotinib as a combination therapy in patients having tumors harboring activating GNAQ or GNA11 hotspot mutations.

For each of the IDE196/binimetinib and IDE196/crizotinib combination arms of the clinical trial, we have established a joint development committee, and there will be joint decision making and data sharing of the clinical trial results between the parties. We will sponsor the clinical studies and Pfizer will provide the binimetinib and crizotinib drug supply. If there is clinical data from the collaboration studies that could be used to obtain regulatory approvals or label changes, we will enter into good faith negotiations with Pfizer to determine a regulatory submission strategy.

Public Offering and Sale of IDEAYA Common Stock

On June 22, 2020, we closed on an underwritten public offering, or the Offering, of 6,666,667 shares of our common stock at an offering price of $15.00 per share, pursuant to which we received gross proceeds of $100.0 million, before deducting underwriting discounts and commissions and other offering expenses.

On July 22, 2020, as part of the Offering, the Company sold and issued an additional 500,000 shares of common stock upon the exercise of the overallotment option by the underwriters for gross proceeds of $7.5 million before deducting underwriting discounts and commissions and other offering. We realized aggregate gross proceeds of $107.5 million from the Offering, including gross proceeds from the sale of shares in the base Offering and the sale of shares from exercise of the overallotment option, and before deducting underwriting discounts and commissions and other offering expenses payable by us.

Private Placement of IDEAYA Common Stock with GSK

On June 17, 2020, we entered into a stock purchase agreement with Glaxo Group Limited, or GGL, an affiliate of GlaxoSmithKline, pursuant to which GGL agreed to purchase in a private placement, subject to certain conditions, 1,333,333 shares of our common stock at a price per share of $15.00, which is equal to the public offering price per share in the Offering. The common stock sold pursuant thereto was not registered under the Securities Act of 1933, as amended, or the Securities Act. The closing of this private placement occurred on August 3, 2020, following HSR Clearance of the associated GSK Collaboration Agreement, described below, and satisfaction of other certain customary closing conditions, pursuant to which we received proceeds of $20.0 million.

On August 3, 2020, following HSR Clearance of the associated GSK Collaboration Agreement, we closed on the private placement of 1,333,333 shares of our common stock to Glaxo Group Limited, or GGL, an affiliate of GlaxoSmithKline, at a price per share of $15.00, which is equal to the public offering price per share in the Offering. The common stock sold pursuant thereto was not registered under the Securities Act of 1933, as amended, or the Securities Act. We received proceeds of $20.0 million from the sale of these shares in this private placement.

Prospectus Supplement - At-the-Market Facility

On August 12, 2020, we filed a prospectus supplement to the prospectus dated June 10, 2020, activating our at-the-market, or ATM, facility by entering into a sales agreement with Jefferies LLC, or Jefferies, relating to shares of our common stock offered by the prospectus supplement and the accompanying prospectus. Pursuant to the terms of the sales agreement, we may offer and sell shares of our common stock, $0.0001 par value per share, having an aggregate offering price of up to $50,000,000 from time to time through Jefferies acting as agent. During the three months ended September 30, 2020, we did not make any sales under the ATM facility.

Corporate Update

We do not have any products approved for sale and have not generated any revenue since inception. We have funded our operations through September 30, 2020 primarily through the sale and issuance of common stock, redeemable convertible preferred stock, and convertible promissory notes. In May 2019, we completed our initial public offering, or IPO. In June and July 2020, we added an aggregate of $227.5 million to our balance sheet from a follow-on public offering of $107.5 million in gross proceeds, a direct private placement equity investment by GGL with $20.0 million in gross proceeds, and a non-dilutive upfront cash payment of $100 million from GSK.

Since our inception in June 2015, we have devoted substantially all of our resources to discovering and developing our product candidates. We have incurred significant operating losses to date and expect that our operating expenses will increase significantly as we advance our product candidates through preclinical and clinical development; seek regulatory approval, and prepare for, and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. Certain program costs that contribute to our operating expenses will be reimbursed by GSK pursuant to the GSK Collaboration Agreement, including 100% of costs we incur for research we perform in connection with the Pol Theta program and 80% of the aggregate program costs incurred by us and GSK for research each of us performs for the Werner Helicase program, and if GSK exercises the Option, also the MAT2A program. In addition, we expect to incur additional costs associated with operating as a public company.

Our net losses were $29.4 million and $31.2 million for the nine months ended September 30, 2020 and September 30, 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $121.9 million.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates, ourselves, or for some programs, in collaboration with our strategic partners. We are leading and solely responsible for preclinical, translational and clinical research and development, as applicable, for (i) the IDE196 monotherapy arm of our IDE196-001 clinical trial, (ii) our PARG program and (iii) our DNA Damage Target or DDT program. We are leading clinical development in the ongoing IDE196 / binimetinib combination arm and the planned IDE196/crizotinib combination arm of our IDE196-001 clinical trial, in each case in coordination with Pfizer pursuant to the Clinical Trial Collaboration and Supply Agreement. We are leading preclinical development and plan to lead early-stage clinical development for evaluation of IDE397 in a clinical trial which we plan to initiate in the first half of 2020, in coordination with GSK pursuant to the GSK Collaboration Agreement. We are collaborating with GSK on preclinical research for our Pol Theta and Werner Helicase programs, pursuant to the GSK Collaboration Agreement.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

As of September 30, 2020, we had cash, cash equivalents and marketable securities of $288.8 million.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our planned operations for at least 12 months from the date of the issuance of these financial statements.

These funds will support our efforts through potential achievement of multiple preclinical and clinical milestones across multiple programs. Anticipated clinical milestones in our synthetic lethality pipeline include Phase 1 monotherapy interim data for IDE397, our MAT2A inhibitor development candidate, Phase 1 monotherapy interim data for our Pol theta inhibitor development candidate, which we are targeting to designate in 2021, and Phase 1 initiation for our PARG inhibitor development candidate, which we are targeting to select in 2021. Anticipated clinical milestones for our IDE196 Phase 1/2 clinical trial include initiation of a Phase 1 dose escalation arm of our clinical trial for evaluating IDE196 and crizotinib as combination therapy in the first half of 2021, expansion of IDE196 / binimetinib combination arm of clinical trial, interim data for IDE196 monotherapy in MUM and other GNAQ/11 solid tumors, as well as interim data for IDE196 and binimetinib as combination therapy in 2021.

Components of Operating Results

Collaboration Revenues

To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future. Our revenue primarily consists of collaboration revenue under the GSK Collaboration Agreement, including amounts that are recognized related to upfront payments and amounts due to us for research and development services. In the future, revenue may include additional milestone payments, option exercise payments, profit sharing, and royalties on any net product sales under our collaborations. We expect that any revenue we generate will fluctuate from period to period as a result of the timing and amount of license, research and development services, and milestone and other payments.

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with discovery and development of our product candidates. These expenses include certain payroll and personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expenses for our research and product development employees, fees to third parties to conduct certain research and development activities on our behalf including fees to CMOs and CROs in support of manufacturing and clinical activity for IDE 196, consulting costs, costs for laboratory supplies, costs for product licenses and allocated overhead, including rent, equipment, depreciation, information technology costs and utilities. We expense both internal and external research and development expenses as they are incurred.

We have entered into various agreements with CMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered.

Costs of certain activities, such as preclinical studies, are generally recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheet. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We are focusing substantially all of our resources on the development of our product candidates. We expect our research and development expenses to increase substantially during the next few years, as we seek to initiate clinical trials for our product candidates, complete our clinical program, pursue regulatory approval of our product candidates and prepare for a possible commercial launch. Predicting the timing or the cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expense, professional fees for legal, patent, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase, as a result of increased personnel costs, including salaries, benefits and stock-based compensation expense, patent costs for our product candidates, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining compliance with our NASDAQ stock exchange listing and requirements of the Securities and Exchange Commission, or the SEC, investor relations costs and director and officer insurance policy premiums associated with being a public company.

Other Income (Expense)

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Results of Operations

Comparison of Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,			
	2020	2019	Change	% Change
Revenue:				
Collaboration revenue	$ 8,967	$ —	$ 8,967	100%
Operating expenses:				
Research and development	10,025	8,923	1,102	12%
General and administrative	3,938	2,700	1,238	46%
Loss from operations	(4,996)	(11,623)	6,627	57%
Interest income and other income (expense), net	70	654	(584)	(89%)
Net loss	$ (4,926)	$ (10,969)	$ 6,043	55%

Collaboration Revenue

Collaboration revenue increased by $9.0 million in the three months ended September 30, 2020. In July 2020, the GSK Collaboration Agreement became effective, and we started recognizing collaboration revenue, which consists of revenue from preclinical and Phase 1 monotherapy clinical research and development services under the MAT2A program as well as preclinical research services and the related license under the Pol Theta and WRN programs. Collaboration revenue recognized in the three months ended September 30, 2020 also included revenue from the exercise by GSK of the material right associated with the option to license IDEAYA-owned technology under the MAT2A program to the extent necessary for preclinical activities.

Research and Development Expenses

Research and development expenses increased by $1.1 million, or 12%, from the three months ended September 30, 2019 to the three months ended September 30, 2020. The increase in research and development expenses was primarily due to an increase in fees to CROs of $1.2 million as well as fees to contractors of $0.5 million related to support costs for our Phase 1/2 clinical trial to evaluate IDE196 in solid tumors, the advancement of our lead product candidates through preclinical studies and regulatory support activity, which was partially offset by a decrease in costs for laboratory supplies used in support of our research programs of $0.4 million and a decrease in payroll expenses, including salaries, benefits and stock-based compensation expense, of $0.2 million.

General and Administrative Expenses

General and administrative expenses increased by $1.2 million, or 46%, from the three months ended September 30, 2019 to the three months ended September 30, 2020. The increase in general and administrative expenses was primarily due to an increase in payroll expenses, including salaries, benefits and stock-based compensation expense, of $0.9 million related to increased headcount to support our growth as a public company and an increase in consulting expenses of $0.2 million related to human resources, accounting and information technology projects.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net decreased by $0.6 million, or 89%, from the three months ended September 30, 2019 to the three months ended September 30, 2020, primarily due to a decrease in interest rate yields on our cash, cash equivalents and marketable securities balances during the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

Comparison of Nine months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the periods indicated (in thousands):

	Nine Months Ended September 30,			%
	2020	**2019**	**Change**	**Change**
Revenue:				
Collaboration revenue	$ 8,967	$ —	$ 8,967	100%
Operating expenses:				
Research and development	27,647	25,778	1,869	7%
General and administrative	11,384	7,174	4,210	59%
Loss from operations	(30,064)	(32,952)	2,888	9%
Interest income and other income (expense), net	704	1,758	(1,054)	(60%)
Net loss	$ (29,360)	$ (31,194)	$ 1,834	6%

Collaboration Revenue

Collaboration revenue increased by $9.0 million in the nine months ended September 30, 2020. In July 2020, the GSK Collaboration Agreement became effective, and we started recognizing collaboration revenue, which consists of revenue from preclinical and Phase 1 monotherapy clinical research and development services under the MAT2A program as well as preclinical research services and the related license under the Pol Theta and WRN programs. Collaboration revenue recognized in the nine months ended September 30, 2020 also included revenue from the exercise by GSK of the material right associated with the option to license IDEAYA-owned technology under the MAT2A program to the extent necessary for preclinical activities.

Research and Development Expenses

Research and development expenses increased by $1.9 million, or 7%, from the nine months ended September 30, 2019 to the nine months ended September 30, 2020. The increase in research and development expenses was primarily due to an increase in fees to CROs of $3.3 million as well as fees to contractors of $1.1 million related to support costs for our Phase 1/2 clinical trial to evaluate IDE196 in solid tumors and the advancement of our lead product candidates through preclinical studies, which was partially offset by a decrease in payroll expenses, including salaries, benefits and stock-based compensation expense, of $1.4 million, and a decrease in costs for laboratory supplies used in support of our research programs of $1.4 million.

General and Administrative Expenses

General and administrative expenses increased by $4.2 million, or 59%, from the nine months ended September 30, 2019 to the nine months ended September 30, 2020. The increase in general and administrative expenses was primarily due to an increase in payroll expenses, including salaries, benefits and stock-based compensation expense, of $2.3 million related to increased headcount to support our growth as a public company, an increase in D&O insurance policy premiums of $0.9 million as a public company, an increase in legal expense of $0.3 million related to an increase in patent filings, an increase in costs associated with the filing of a shelf registration statement on Form S-3 of $0.2 million, and an increase in consulting expenses of $0.2 million related to human resources and information technology projects.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net decreased by $1.1 million, or 60%, from the nine months ended September 30, 2019 to the nine months ended September 30, 2020, primarily due to a decrease in interest rate yields on our cash, cash equivalents and marketable securities balances during the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

We have funded our operations primarily through the sale and issuance of common stock, redeemable convertible preferred stock, and convertible promissory notes, as well as the up-front payment received from GSK. As of September 30, 2020, we had cash, cash equivalents and marketable securities of $288.8 million, consisting primarily of money market funds, U.S. government securities, commercial paper, and corporate bonds.

Future Funding Requirements

We have incurred net losses since our inception. For the nine months ended September 30, 2020 and September 30, 2019, we had net losses of $29.4 million and $31.2 million, respectively, and we expect to incur substantial additional losses in future periods. As of September 30, 2020, we had an accumulated deficit of $121.9 million. Based on our current business plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations for at least 12 months from the date of the issuance of these financial statements.

To date, we have not generated any product revenue. We do not expect to generate any meaningful product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, it will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we expect to incur additional costs associated with operating as a public company.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;

- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates;
- potential delays in our ongoing clinical programs as a result of the COVID-19 pandemic;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company; and
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

Adequate additional funding may not be available to us on acceptable terms or at all. See the section of this Quarterly Report titled “Part II, Item 1A – Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents, and restricted cash for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2020	**2019**
Net cash provided by (used in):		
Operating activities	$ 67,059	$ (30,607)
Investing activities	(141,689)	(1,622)
Financing activities	121,801	50,572
Net increase in cash, cash equivalents and restricted cash	$ 47,171	$ 18,343

Cash Flows from Operating Activities

Net cash provided operating activities was $67.1 million for the nine months ended September 30, 2020. Cash provided by operating activities was primarily due to an increase in contract liability of $91.0 million as a result of the up-front payment received from GSK, stock-based compensation expense of $2.6 million, an increase of accrued and other liabilities of $1.2 million due to fees to CROs and CMOs in support of research and manufacturing activities and an increase in accrued payroll expenses due to increased headcounts, depreciation and amortization expense of $1.0 million and an increase in accounts payable of $0.7 million due to fees to CROs and CMOs in support of research and manufacturing activities, partially offset by the use of funds in our operations to develop our product candidates resulting in a net loss of $29.4 million.

Net cash used in operating activities was $30.6 million for the nine months ended September 30, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $31.2 million, adjusted for the net amortization of premiums and discounts on marketable securities of $0.5 million and an increase in prepaid expenses and other assets of $2.1 million mainly due to advance payment for director's and officers' liability insurance premiums and CRO fees, partially offset by depreciation and amortization expense of $0.9 million and stock-based compensation expense of $1.4 million, and an increase in accrued and other liabilities of $1.0 million mainly due to fees to CMOs in support of manufacturing activity for IDE196 and for external research and personnel-related expenses.

Cash Flows from Investing Activities

Net cash used in investing activities was $141.7 million for the nine months ended September 30, 2020, which consisted of $214.4 million used to purchase marketable securities and $0.3 million used to purchase property and equipment, partially offset by $73.0 million provided by maturities of marketable securities.

Net cash used in investing activities was $1.6 million for the nine months ended September 30, 2019, which consisted of $86.1 million used to purchase marketable securities and $1.1 million used to purchase property and equipment, offset by $67.5 million provided by maturities of marketable securities and $18.1 million from sales of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $121.8 million for the nine months ended September 30, 2020, which consisted of $100.7 million of net proceeds from our follow-on offering, $20.0 million of net proceeds from our private placement of common stock, $1.0 million of proceeds from exercise of common stock options, and $0.1 million of proceeds from ESPP purchase.

Net cash provided by financing activities was $50.6 million for the nine months ended September 30, 2019, which consisted primarily of $50.2 million of net proceeds from our IPO.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations" in our Annual Report on Form 10-K filed with the SEC on March 24, 2020.

We lease our laboratory and office facilities in South San Francisco, California under a non-cancelable operating lease with an expiration date in July 2024, dated August 26, 2016 and amended in May 2018. In September 2019, we further amended our South San Francisco facility lease agreement to expand the size of the premises by adding 5,588 rentable square feet of additional space, which we took possession of in August 2020 ("Second Expansion"). The Second Expansion increased our operating lease obligations by $1.2 million as of September 30, 2019. Other than the increase in our operating lease obligations due to the Second Expansion, there have been no material changes in our contractual obligations and commitments since December 31, 2019.

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 in the rules and regulations of the SEC.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" in our Annual Report on Form 10-K filed with the SEC on March 24, 2020, and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the nine months ended September 30, 2020, except as described in Note 2 to the unaudited interim condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K filed with the SEC on March 24, 2020.

Revenue Recognition

We follow Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation.

We apply the five-step model to contracts when (1) parties have approved the contract and are committed to performing respective obligations, (2) we can identify each party's rights regarding the goods or services to be transferred, (3) we can identify the payment terms for the goods or services to be transferred, (4) the contract has commercial substance, and (5) it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, we assess the goods or services promised within each contract and determine the performance obligations by assessing whether each promised good or service is distinct. Goods or services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligations when (or as) the performance obligations are satisfied. We constrain our estimate of the transaction price up to the amount (the "variable consideration constraint") that a significant reversal of recognized revenue is not probable.

Licenses of intellectual property: If a license to our intellectual property is determined to be distinct from the other promised goods or services identified in an arrangement, we recognize revenue from non-refundable, upfront fees allocated to the license at the point in time when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other goods or services, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress toward satisfying the performance obligation for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition.

Customer options for additional goods or services: If a contract contains customer options that allow the customer to acquire additional goods or services, including a license to our intellectual property, the goods and services underlying the customer options are evaluated to determine whether they are deemed to represent a material right. In determining whether the customer option has a material right, we assess whether there is an option to acquire additional goods or services at a discount. If the customer option is determined not to represent a material right, the option is not considered to be a performance obligation. If the customer option is determined to represent a material right, the material right is recognized as a separate performance obligation. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until the option is exercised.

Milestone payments: At the inception of each arrangement or amendment that includes development, regulatory or commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. ASC 606 prescribes two methods to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for us to use the same approach for all contracts. If it is probable that a significant revenue reversal would not occur when the uncertainty associated with the milestone is resolved, the associated milestone value is included in the transaction price. Milestone payments that are highly susceptible to factors outside our influence, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. If there is more than one performance obligation, the transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. We recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability or achievement of each milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees are recorded as contract liabilities upon receipt or when due and may require deferral of revenue recognition to a future period until we perform its obligations under these arrangements. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional. Amounts payable to us and not yet billed to the collaboration partner are recorded as contract assets. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Contractual cost sharing payments received from a customer or collaboration partner are accounted for as variable consideration. We include an expected value in the transaction price. Contractual cost sharing payments received from a customer or collaboration partner are accounted for as variable consideration. We include an expected value in the transaction price. Contractual cost sharing payments made to a customer or collaboration partner are accounted for as a reduction to the transaction price if such payments are not related to distinct goods or services received from the customer or collaboration partner.

Contracts may be amended to account for changes in contract specifications and requirements. Contract modifications exist when the amendment either creates new, or changes existing, enforceable rights and obligations. When contract modifications create new performance obligations and the increase in consideration approximates the standalone selling price for goods and services related to such new performance obligations as adjusted for specific facts and circumstances of the contract, the modification is accounted for as a separate contract. If a contract modification is not accounted for as a separate contract, we account for the promised goods or services not yet transferred at the date of the contract modification (the remaining promised goods or services) prospectively, as if it were a termination of the existing contract and the creation of a new contract, if the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification. We account for a contract modification as if it were a part of the existing contract if the remaining goods or services are not distinct and, therefore, form part of a single performance obligation that is partially satisfied at the date of the contract modification. In such case the effect that the contract modification has on the transaction price, and on the entity's measure of progress toward complete satisfaction of the performance obligation, is recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) at the date of the contract modification (the adjustment to revenue is made on a cumulative catch-up basis).

Upfront payment contract liabilities resulting from our license and collaboration agreements do not represent a financing component as the payment is not financing the transfer of goods and services, and the technology underlying the licenses granted reflects research and development expenses already incurred by us. As such, we do not adjust its revenues for the effects of a significant financing component.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of September 30, 2020, we had cash equivalents and marketable securities of $288.7 million, consisting of interest-bearing money market funds, investments in U.S. government securities, commercial paper, and corporate bonds, for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents and marketable securities, an immediate 10% change in interest rates would not have a material effect on the fair value of our cash equivalents and marketable securities.

We do not believe that inflation, interest rate changes or exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of 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 (the “Exchange Act”)). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2020.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(e) and 15d-15(e) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, cash flows, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, growth prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Summary of Principal Risks Associated with Our Business

- We are an early-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability;
- We are very early in our development efforts. Our business is dependent on the successful development of our product candidates, future product candidates, and companion diagnostics for biomarkers associated with our product candidates and future product candidates;
- In connection with the Collaboration, Option and License Agreement with GSK, if GSK does not exercise its option or if it terminates any development program under its collaborations with us, whether as a result of our inability to meet milestones or otherwise, any potential revenue from those collaborations will be significantly reduced or eliminated, and our results of operations and financial condition will be materially and adversely affected.
- As an organization, we have never conducted a clinical trial, and may be unable to do so for any of our product candidates;
- The successful development of targeted therapeutics, including therapeutics involving direct targeting of an oncogenic pathway and synthetic lethality therapeutics, including our portfolio of synthetic lethality small molecule inhibitors, as well as any related diagnostics, is highly uncertain;
- Preclinical and clinical drug development is a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our business, financial condition, results of operations and prospects. Furthermore, results of earlier studies and trials may not be predictive of future trial results;
- We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being developed. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected;

- If we are unable to successfully develop molecular diagnostics for biomarkers that enable patient selection and/or that demonstrate drug-target interaction, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates;
- We rely on third parties for the manufacture of our product candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts;
- We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete;
- If we fail to attract and retain senior management and key scientific personnel, our business may be materially and adversely affected;
- The COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely affect our business and operations, including the pace of enrollment in current or future clinical trials;
- Our success depends on our ability to obtain and maintain protection for our intellectual property and our proprietary technologies and to avoid infringing the rights of others; and
- Our stock price has been and may continue to be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

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

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

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are an early-stage biopharmaceutical company, and we have only a limited operating history upon which you can evaluate our business and prospects. We currently have no products approved for commercial sale, have not generated any revenue from sales of products and have incurred losses in each year since our inception in June 2015. In addition, we have limited experience as a company and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Only one of our product candidates, IDE196, is currently in ongoing clinical trials – one ongoing Phase 1 clinical trial conducted and controlled by Novartis and one ongoing Phase 1/2 clinical trial that we initiated in June 2019 to evaluate IDE196 in solid tumors harboring GNAQ or GNA11 hotspot mutations.

We have had significant operating losses since our inception. Our net losses for the nine months ended September 30, 2020 and September 30, 2019 were $29.4 million and $31.2 million, respectively. As of September 30, 2020, we had an accumulated deficit of $121.9 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. One of our product candidates, IDE196, is currently in a Phase 1 clinical trial being conducted by Novartis and in a Phase 1/2 clinical trial we are conducting. We have multiple other product candidates in preclinical development, as well as early-stage research programs. Our product candidates will require substantial additional development time and resources before we will be able to apply for or receive regulatory approvals and, if approved, begin generating revenue from product sales. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. We also do not yet have a sales organization or commercial infrastructure and, accordingly, we will incur significant expenses to develop a sales organization or commercial infrastructure in advance of regulatory approval and generating any commercial product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop IDE196, our other product candidates and any future product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

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

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

- the timing and cost of, and level of investment in, research, development and commercialization activities, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the timing of regulatory approvals, if any, in the United States and internationally;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity of productions, and the terms of any agreements we enter into with third-party suppliers;
- timing and amount of any option exercise, milestone, royalty or other payments we may or may not receive pursuant to any current or future collaboration or license agreement, including under the Collaboration, Option and License Agreement with GSK;
- timing and amount of any milestone, royalty or other payments due under any current or future collaboration or license agreement, including the License Agreement with Novartis or the Option and License Agreement with Cancer Research UK and University of Manchester;
- coverage and reimbursement policies with respect to any future approved products, and potential future drugs that compete with our products;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the level of demand for any future approved products, which may vary significantly over time;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or collaboration partners.

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

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

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

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our precision medicine target and biomarker discovery platform and our initial preclinical and clinical product candidates. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. As of September 30, 2020, we had cash, cash equivalents and marketable securities of $288.8 million. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the research and development of our precision medicine target and biomarker discovery platform, clinical and preclinical product candidates, and any other future product candidates we may choose to pursue, as well as other corporate uses. Specifically, in the near term, we expect to incur substantial expenses as we advance our synthetic lethality product candidates through preclinical studies, advance IDE196 through clinical development, begin clinical development for IDE397, seek regulatory approval, prepare for and, if approved, proceed to commercialization, and continue our research and development efforts. These expenses will include our cost sharing obligations with GSK for research and development for our WRN program and MAT2A program (if GSK exercises its exclusive option to obtain an exclusive license to continue development of and commercialize MAT2A products). These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully develop and commercialize our product candidates or any future product candidates.

We believe that our existing cash, cash equivalents and marketable securities will allow us to fund our planned operations for at least 12 months from the date of the issuance of the financial statements included in this Form 10-Q. However, our operating plans and other demands on our capital resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may adversely affect our business. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. Attempting to secure additional financing may also divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of developing our product candidates or any other future product candidates, and conducting preclinical studies and clinical trials, including our ongoing IDE196 Phase 1/2 clinical trial in solid tumors harboring GNAQ or GNA11 mutations;
- the scope, progress, results and costs related to the research and development of our precision medicine target and biomarker discovery platform, including costs related to the development of our proprietary libraries and database of tumor genetic information and specific cancer-target dependency networks;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates or any future product candidates, or any applicable diagnostics;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of developing, in collaboration with certain diagnostic companies, diagnostics for biomarkers associated with our product candidates or any other future product candidates in support of our preclinical studies and clinical trials, including our ongoing Phase 1/2 clinical trial for IDE196 in solid tumors harboring GNAQ or GNA11 mutations;

- the cost of coordinating and/or collaborating with certain diagnostic companies for manufacturing and supply of companion diagnostics for biomarkers associated with our product candidates and any future product candidates;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the Collaboration, Option and License Agreement with GSK, the License Agreement with Novartis and the Option and License Agreement with Cancer Research United Kingdom, or Cancer Research UK, and University of Manchester;
- the timing and amount of any option exercise, milestone, royalty or other payments we may or may not receive pursuant to any current or future collaboration or license agreement, including under the Collaboration, Option and License Agreement with GSK;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreement, including under the License Agreement with Novartis or the Option and License Agreement with Cancer Research UK and University of Manchester;
- potential delays in our ongoing clinical programs as a result of the COVID-19 pandemic;
- the cost of manufacturing our product candidates and any future products we successfully commercialize;
- the cost of commercialization activities, including the cost of building a sales force in anticipation of product commercialization and distribution costs;
- any product liability or other lawsuits related to our product candidates or future approved products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products, if any.

Our ability to raise additional funds will depend on financial, economic and other factors, including the ongoing effects of the COVID-19 pandemic, many of which are beyond our control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize IDE196, if approved, or any other future approved products, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies.

To date, we have primarily financed our operations through the sale of equity securities and payments received under our collaboration agreements. We will be required to seek additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders may suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights or jointly own some aspects of our technologies or product candidates that we would otherwise pursue on our own.

Risks Related to Our Business

We are early in our development efforts. Our business is dependent on the successful development of our product candidates, future product candidates, and companion diagnostics for biomarkers associated with our product candidates and future product candidates.

Our current product candidates are in early stages of development and we are further developing our precision medicine target and biomarker discovery platform. We have no products approved for sale and our most advanced product candidate, IDE196, is in the early stages of clinical development and will require additional clinical development, regulatory review and approval in each jurisdiction in which we intend to market it, access to sufficient commercial manufacturing capacity, and significant sales and marketing efforts before we can generate any revenue from product sales. IDE196 is currently being evaluated in an ongoing Phase 1/2 clinical trial in patients having tumors with GNAQ or GNA11 hotspot mutations, that we initiated in June 2019, including the combination arm with binimetinib that we initiated in June 2020. IDE196 is also being tested in an earlier-initiated, ongoing Phase 1 clinical trial conducted by Novartis in patients with metastatic uveal melanoma. Our other product candidates have not been tested in clinical trials. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. In the future, we may also become dependent on other product candidates that we may develop or acquire; however, given our early stage of development, it may be many years, if at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to support approval for commercialization.

We have not previously submitted a new drug application, or NDA, to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in select foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of drugs, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The clinical and commercial success of our current and any future product candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to develop and successfully utilize our precision medicine target and biomarker discovery platform;
- timely and successful completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- acceptance of investigational new drug applications, or INDs, by the FDA, or similar regulatory filing by a comparable foreign regulatory authority for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- whether we are required by the FDA or a comparable foreign regulatory agency to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates;
- our ability to timely execute our ongoing clinical trials and enroll a sufficient number of patients on a timely basis, particularly in light of the effects of the COVID-19 pandemic, to evaluate the potential of our product candidates in clinical development;
- acceptance of our proposed indications and primary endpoint assessments of our product candidates by the FDA and comparable foreign regulatory authorities;
- the availability or successful development of companion diagnostics for biomarkers associated with our product candidates or any other future product candidates;
- our ability to make arrangements with third-party manufacturers for, or establish, commercial manufacturing capabilities, and to consistently manufacture our product candidates on a timely basis;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy and acceptable risk-benefit profile of our product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, either as monotherapy or in combination with other drugs, or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and comparable foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our current product candidates or any future product candidates or approved products, if any;
- the willingness of physicians, operators of hospitals and clinics and patients to use or adopt any approved products, as well as the willingness of physicians and other health-care providers to incorporate molecular diagnostics or genetic sequencing into their clinical practice;
- our ability to successfully develop a commercial strategy and thereafter commercialize any approved products in the United States and internationally, whether alone or in collaboration with others;
- the availability and level of coverage and adequate reimbursement from managed care plans, private insurers, government payors, such as Medicare and Medicaid, and other third-party payors for any of our product candidates that may be approved;
- the convenience of our treatment or dosing regimen;
- our ability to compete with other approved therapies, if any;

- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidate or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for any approved products;
- our ability to establish and enforce intellectual property rights in and to our product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

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

In connection with the Collaboration, Option and License Agreement with GSK, if GSK does not exercise its option or if it terminates any development program under its collaborations with us, whether as a result of our inability to meet milestones or otherwise, any potential revenue from those collaborations will be significantly reduced or non-existent, and our results of operations and financial condition will be materially and adversely affected.

We have invested a significant portion of our time and financial resources in the development of multiple product candidates that are included in our strategic partnership and collaboration with GSK, under the Collaboration, Option and License Agreement entered into on June 15, 2020, or the GSK Collaboration Agreement. The programs included in the GSK Collaboration Agreement are the MAT2A, Pol Theta (POLQ) and Werner Helicase (WRN) programs. Our ability to continue to advance these synthetic lethality programs in development, in particular prior to the exercise by GSK of its exclusive option to obtain an exclusive license to continue development of and commercialize MAT2A products, is highly dependent on achieving certain development milestones in these programs and triggering related milestone fee payments to us.

Under the GSK Collaboration Agreement, within a specified time period after we deliver to GSK a data package from our MAT2A Phase 1 monotherapy clinical trial, GSK is entitled to exercise an option to obtain an exclusive license for continued development and commercialization of MAT2A products arising out of the MAT2A program on a worldwide basis, which we refer to as the Option. GSK's exercise of the Option may be subject to Hart-Scott-Rodino clearance, or HSR Clearance, therefor at such time of exercise. After GSK exercises the Option and, if required, HSR Clearance is obtained, GSK must pay us an option exercise payment of $50.0 million.

Under the GSK Collaboration Agreement, we are eligible to receive from GSK future development and regulatory milestones of up to $465.0 million for each MAT2A product, and up to $485.0 million for each POLQ and WRN product, and commercial milestones of up to $475.0 million, with respect to each MAT2A (if GSK exercises the Option and receives HSR Clearance with respect thereto), POLQ and WRN product. Additionally, we are entitled to receive 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of MAT2A (if GSK exercises the Option and receives HSR Clearance with respect thereto) and WRN products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions. We are entitled to receive tiered royalties on global net sales of POLQ products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions. We have a right to opt-out of the 50% U.S. net profit share and corresponding development cost share for either or both the MAT2A and WRN programs, and would be eligible to receive tiered royalties on U.S. net sales of MAT2A or WRN products, as applicable, by GSK, its affiliates and their sublicensees at the same royalty rates as for global non-U.S. net sales thereafter, with potential positive economic adjustments based on the stage of the MAT2A or WRN program, as applicable, at the time of opt-out. There is no guarantee that we will be able to successfully continue to advance the POLQ and WRN programs and receive regulatory filing milestone payments related to any POLQ or WRN product. There is no guarantee that we will be able to advance a MAT2A product to or successfully conduct the MAT2A Phase 1 monotherapy clinical trial. Even if we successfully advance a MAT2A product and conduct the MAT2A Phase 1 monotherapy clinical trial, GSK is under no obligation to

exercise the Option. Further, in the event that GSK is required to obtain HSR Clearance after exercising the Option, and such HSR Clearance is not obtained, GSK will not participate in further development of any MAT2A products and the product rights would revert to us. We would then have worldwide rights to those assets and be responsible for funding the development of the assets. GSK may terminate the entire GSK Collaboration Agreement or any collaboration program on a target-by-target basis for any or no reason upon written notice to us after expiration of a defined notice period. The GSK Collaboration Agreement or any program under the GSK Collaboration Agreement may also be terminated by either party for the other party's insolvency or certain uncured breaches. We may terminate the GSK Collaboration Agreement if GSK or any of its sublicensees or affiliates challenge certain of our patents. Depending on the timing of any such termination we may not be entitled to receive the option exercise fees, or potential milestone payments, as these payments terminate with termination of the GSK Collaboration Agreement.

If GSK does not exercise the Option with respect to any MAT2A product (or HSR Clearance thereof is not obtained), or terminates its rights and obligations with respect to a program or the entire GSK Collaboration Agreement, then depending on the timing of such event:

- the development of our product candidates subject to the GSK Collaboration Agreement may be terminated or significantly delayed;
- our cash expenditures could increase significantly if it is necessary for us to hire additional employees and allocate scarce resources to the development and commercialization of product candidates that were previously funded by GSK;
- we would bear all of the risks and costs related to the further development and commercialization of product candidates that were previously the subject of the GSK Collaboration Agreement, including the reimbursement of third parties; and
- in order to fund further development and commercialization, we may need to seek out and establish alternative collaboration arrangements with third-party collaboration partners; this may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs or increase our expenditures and seek additional funding by other means.

Any of these events would have a material adverse effect on our results of operations and financial condition.

Clinical development of our lead product candidate, IDE196, depends, in part, on data from Novartis' ongoing Phase 1 clinical trial of IDE196 in patients with metastatic uveal melanoma. We have no control over the execution of Novartis' trial.

Our most advanced product candidate, IDE196, is currently being evaluated in a Phase 1 clinical trial conducted by Novartis. Novartis' ongoing clinical trial has two arms – a monotherapy arm, and a combination arm evaluating IDE196 in combination with Novartis' p53-MDM2 inhibitor, HDM201. Our license agreement with Novartis provides that we may reference clinical data from the monotherapy arm and safety data from both arms of Novartis' ongoing clinical trial in our regulatory filings. Updated monotherapy data from Novartis was presented at AACR in April 2019.

We have no control or oversight over the design or implementation of Novartis' clinical trial. The license agreement does not impose obligations on Novartis with respect to the conduct of the ongoing Phase 1 clinical trial, its timing, or whether Novartis must complete it. Novartis may delay or discontinue the monotherapy arm and/or the combination arm of their ongoing clinical trial at their own discretion as the trial progresses. Failure on behalf of Novartis, or any third parties with which Novartis has separately contracted with respect to the trial, to adhere to the trial protocols, GCP or applicable regulations may delay Novartis' clinical trial, lead to Novartis' discontinuation of the trial, or cause the results of the trial to be unacceptable for use in a submission by us to the FDA or a comparable regulatory authority. Furthermore, HDM201 is still in clinical development and has not been approved. If Novartis encounters any clinical or regulatory difficulty with regard to HDM201, it may result in the delay or the complete discontinuation of the combination arm of the trial. If Novartis' clinical trial is delayed or discontinued for any reason, or if we identify another issue with Novartis' data, it may delay our development of IDE196, or make it

difficult or impossible for us to rely on Novartis' clinical data in regulatory filings as planned. Furthermore, although the agreement requires Novartis to provide us with certain data at specified intervals, if Novartis does not make data available to us, our IDE196 development program may be significantly delayed and we may need to conduct additional studies or trials independently. As a result, we may not be able to obtain regulatory approval for IDE196 in a timely fashion, at the expected cost to us, or at all, and our business, financial position, results of operations and prospects may be adversely affected.

As an organization, we have never completed a clinical trial, and may be unable to do so for any of our product candidates.

We will need to successfully initiate and complete our own Phase 1 clinical trials and later-stage and pivotal clinical trials in order to obtain FDA or a comparable foreign regulatory body's approval to market our product candidates. Carrying out clinical trials and the submission of regulatory filings is a complicated process. As an organization, we have not yet completed any clinical trials for any of our product candidates. Our lead product candidate, IDE196, is in a Phase 1/2 clinical trial that we are conducting. We have limited experience in preparing, submitting and prosecuting regulatory filings, and have not previously submitted any NDA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many additional clinical trials of IDE196 or how many clinical trials of any of our other product candidates will be required or whether the FDA will agree with the design or implementation of our clinical trials. We are required to comply with certain regulatory requirements, and the FDA may identify specific clinical or other development-related requirements that we must satisfy, as a condition to initiating or continuing our clinical trials; if we fail to meet such a requirement, the FDA may issue a clinical hold or designate other conditions on our clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission of a marketing application for, and approval of IDE196 or any of, our other product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing IDE196 or any other product candidate.

The successful development of targeted therapeutics, including therapeutics involving direct targeting of an oncogenic pathway and synthetic lethality therapeutics, including our portfolio of synthetic lethality small molecule inhibitors, as well as any related diagnostics, is highly uncertain.

Successful development of targeted therapeutics, including therapeutics involving direct targeting oncogenic pathways and synthetic lethality therapeutics, such as our portfolio of synthetic lethality small molecule inhibitors, as well as any related diagnostics, is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Our precision medicine target and biomarker discovery platform is based on new technologies and methods relating to drug target and biomarker identification, screening and validation, including Dual CRISPR genetic screening and bioinformatics and we have not, to date, sought regulatory approval for any therapeutics developed through our precision medicine target and biomarker discovery platform. As such, it is difficult to accurately predict the developmental challenges we or our collaboration partners, such as GSK, may incur for our current and future product candidates as we proceed through product discovery, identification, preclinical studies and clinical trials.

Our precision medicine target and biomarker discovery platform is novel and may not be effective at identifying targets and/or biomarkers for product candidates. We therefore cannot provide any assurance that we will be able to successfully identify additional product candidates or biomarkers, advance any of these additional product candidates or diagnostics for their associated biomarkers through the development process.

Additionally, particular patient genetic alterations, such as mutations, deletions or fusions may not be functionally active genetic drivers of the disease. Further, whether a genetic alteration is functionally active may be difficult to ascertain from preclinical cancer models, may be tissue-type dependent and may vary from patient to patient within a specific indication. If that was the case, we would need to functionally validate such genetic alterations, for example, using *in vitro* and *in vivo* models, potentially across more than one tumor-tissue type and across multiple cell lines. If some of the genetic alterations are not functionally validated, this would reduce the size of our addressable patient population. Even if genetic alterations are preclinically validated, the relevance of these alterations may not translate into a human clinical setting, which could adversely impact our clinical trial results and our commercial opportunities.

Targeted therapeutics that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- research or preclinical studies may show our targeted small molecule inhibitors or antagonists to be less effective than desired or to have harmful or problematic side effects or toxicities;
- failure to accurately identify, validate or develop clinically relevant biomarkers for our targeted therapeutic product candidates;
- clinical trial results may show our targeted therapeutic small molecule inhibitors to be less effective than expected based on preclinical studies (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical trials, patients dropping out of trials, length of time to achieve trial endpoints, additional time requirements for data analysis, IND preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that may make our targeted therapeutic small molecule inhibitors uneconomical; and
- proprietary rights of others and their competing products and technologies that may prevent our targeted therapeutic small molecule inhibitors, or the diagnostics for biomarkers associated with such small molecule inhibitors, from being commercialized.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our precision medicine target and biomarker discovery platform will result in the identification, development, and regulatory approval of any products. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a decision by a regulatory authority may be difficult to predict for targeted therapeutic small molecule inhibitors, in large part because of the limited regulatory history associated with them. The clinical trial requirements of the FDA and other comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. Except for certain PARP inhibitors, no products based on synthetic lethality have been approved to date by regulators. As a result, the regulatory approval process for product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or other comparable regions of the world or how long it will take to commercialize our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market would adversely affect our business, financial condition, results of operations and prospects.

Even if we are successful in obtaining regulatory approval, commercial success of any approved products will also depend in large part on the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost-effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be limited.

In addition, if any of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with cGMPs, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events, or AEs, of unanticipated severity or frequency. Compliance with these requirements is costly and any failure to comply or other post-approval issues with our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical drug development is a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our business, financial condition, results of operations and prospects. Furthermore, results of earlier studies and trials may not be predictive of future trial results.

Before we can initiate clinical trials for our product candidates, we must submit the results of preclinical studies to the FDA or a comparable foreign regulatory authority along with other information, including information about product candidate chemistry, manufacturing and controls, diagnostics for biomarkers for our product candidates and our proposed clinical trial protocol, as part of an IND application or similar regulatory filing. We anticipate submitting an IND to the FDA for our IDE397 development candidate in the fourth quarter of 2020.

Before obtaining marketing approval from regulatory authorities for the sale of any products, we, or our collaboration partners, such as GSK, must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive and can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. In addition, we may rely in part on preclinical, clinical and quality data generated by contract research organizations, or CROs, and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. Further, pursuant to our license agreement with Novartis, we have a right of reference to certain data from Novartis' ongoing Phase 1 clinical trial data for our regulatory filings for IDE196.

If these third parties, including Novartis, fail to make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or trials or collect additional data independently. In either case, our development costs would increase.

Our clinical trial collaboration and supply agreement with Pfizer for the supply of their MEK inhibitor, binimetinib, and their cMET inhibitor, crizotinib, supports our plans to evaluate the safety and efficacy of IDE196 in combination with binimetinib and in combination with crizotinib in Phase 1/2 clinical trial arms that we initiated in June 2020 and that we plan to initiate in late 2020 to early 2021, respectively. If Pfizer delays or fails to supply binimetinib or crizotinib in support of the combination arms of the IDE196 clinical trial, the development program as pertaining to combination of IDE196 with either a MEK inhibitor or a cMET inhibitor may be significantly delayed, and our development costs may increase. Subject to completion of and satisfactory results from preclinical studies, we may evaluate IDE196 in combination with one or more anti-cancer agent(s) in addition to binimetinib and crizotinib, such as a different inhibitor of MEK or cMET or an inhibitor of FAK, mTOR and/or CDK4/6, in a Phase 1/2 clinical trial in patients with metastatic uveal melanoma. This may require us to establish additional supply agreements and rely upon third parties for supply of such combination agents, or if such combination agents

are commercially available, in the absence of a supply agreement, we may incur the cost of purchasing such combination agents and may be at risk of having insufficient supply. We may initiate clinical trials in which our product candidates, including IDE196, are combined with one or more other pharmaceutical agents that have not yet been approved by the FDA or comparable foreign regulatory authorities; in such situations, we may be relying on third parties for obtaining appropriate regulatory approvals and we may have no or limited influence over whether or not such regulatory approvals are achieved for such combination agents.

We and our strategic collaborators, such as GSK, also may experience numerous unforeseen events during, or as a result of, any preclinical studies or clinical trials that could delay or prevent us or our strategic collaborators from successfully developing our product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- the FDA or a comparable foreign regulatory authority disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial, particularly in light of the potential impact of the COVID-19 pandemic on patient enrollment and clinical site closures;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical sites deviating from clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites;
- obtaining sufficient quantities of product candidate for use in preclinical studies or clinical trials from third-party suppliers; or
- accessing third-party products or product candidates for use in combination with our product candidates in preclinical studies or clinical trials, including third-party product candidates that have not yet been approved by the FDA.

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we or our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, or be unable to produce sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;

- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- collaborators, such as GSK, may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

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

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements, which could be expensive and time-consuming; or
- have the treatment removed from the market after obtaining marketing approval.

We and our strategic collaborators, such as GSK, could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or another comparable foreign regulatory authority. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

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

If any of our preclinical studies or clinical trials of our product candidates are delayed or terminated, the commercial prospects of our product candidates may be harmed, and our ability to ultimately generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development and regulatory approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If our product candidates and any future product candidates prove to be ineffective, unsafe or commercially unviable, our entire platform and approach would have little, if any, value, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Furthermore, the results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. Furthermore, for some of our programs, in the future we intend to conduct basket trials, which will be designed to include multiple clinically defined populations under one investigational protocol, although each population is enrolled and analyzed separately. A basket trial design could potentially decrease the time to study new populations by decreasing administrative burden, however, these trials may not provide opportunities for accelerated regulatory pathways, and do not overcome limitations to extrapolating data from the experience in one disease to other diseases, because safety and efficacy results in each indication are analyzed separately. Accordingly, clinical success in a basket trial, or any trial in one indication, may not predict success in another indication. In contrast, in the event of an adverse safety issue, clinical hold, or other adverse finding in one or more indications being tested, such event could adversely affect our trials in the other indications and may delay or prevent completion of the clinical trials. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials for similar indications that we are pursuing due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval of any products.

Synthetic lethality represents an emerging class of precision medicine targets, and negative perceptions of the efficacy, safety or tolerability of this class of targets, including any that we develop, could adversely affect our ability to conduct our business, advance our product candidates or obtain regulatory approvals.

Aside from PARP inhibitors, such as Lynparza, Rubraca, Zejula and Talzenna, no synthetic lethality small molecule inhibitor therapeutics have been approved to date by the FDA or other comparable regulators. AEs in future clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other AEs in the field of synthetic lethality, or other products that are perceived to be similar to synthetic lethality, such as those related to gene therapy or gene editing, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and CROs in our product candidates, and less demand for any product that we may develop. Our substantial pipeline of synthetic lethality small molecule inhibitor product candidates could result in a greater quantity of reportable AEs or other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delays or holds by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our synthetic lethality programs, as well as our business as a whole. In addition, responses by U.S. federal, state or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop any product candidates or commercialize any approved products, obtain or maintain regulatory approval, or otherwise achieve profitability. More restrictive statutory regimes, government regulations, or negative public opinion would have an adverse effect on our business, financial condition, results of operations, and prospects, and may delay or impair the development of our product candidates and commercialization of any approved products or demand for any products we may develop.

Tissue-type agnostic basket trials are an emerging clinical approach, that may result in delays in clinical development, additional regulatory requirements and delays in, or the prevention of, our ability to obtain regulatory approval or commercialize our product candidates.

We initiated a Phase 1/2 tissue-type agnostic basket trial with IDE196 in June 2019, and may also utilize a basket trial approach in clinical trials for other product candidates. Basket trials allow us to evaluate the safety and efficacy of a product candidate in a variety of tumor types with a specific molecular profile. We believe that this clinical approach provides many benefits, however, there are limited precedents, and as a result, there a number of inherent risks.

There is limited precedent for the FDA and foreign regulatory authorities to review and grant tissue-type agnostic approvals. Furthermore, as clinical trials increasingly use classification of tumors by molecular profiling, the FDA or other regulatory authority may change or issue guidance or adopt a policy that adversely affects requirements for basket trials. In the event that such guidance or policy has an effect on any of our protocols or trials, as the case may be, it may result in the delay of clinical development, or require us to conduct additional preclinical studies or clinical trials.

Even if we obtain a tissue-type agnostic approval for one or more of our product candidates, there is limited precedent for obtaining reimbursement. Third-party payors may reimburse at different levels across tumor tissue types and indicates, or not at all.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being developed. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

- the patient eligibility and exclusion criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the clinical trial's primary endpoints;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- the risk that enrolled patients will not complete a clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinical trial investigators' willingness to continue enrolling patients and patients' willingness to complete protocol assessments during the COVID-19 pandemic;
- clinicians' and patients' perceptions as to the safety of the product candidate;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating as well as any drugs under development; and
- our ability to obtain and maintain patient consents.

We will be required to identify and enroll a sufficient number of patients for each of our clinical trials. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or a comparable foreign regulatory authority. In addition, the process of finding and diagnosing patients may prove costly.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. As a result of the COVID-19 pandemic, competition for potential patients in our trials is further exacerbated as a result of multiple clinical site closures. Since the number of qualified clinical investigators is already limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Furthermore, certain conditions for which we plan to evaluate our current development candidates are rare diseases, such as metastatic uveal melanoma, with limited patient pools from which to draw for clinical trials. For example, our lead product candidate, IDE196, is currently being evaluated in a Phase 1/2 basket trial that we initiated in June 2019 to evaluate IDE196 in solid tumors harboring GNAQ/GNA11 hotspot mutations in metastatic uveal melanoma, and potentially in other solid tumors such as cutaneous melanoma and colorectal cancer. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants.

In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed. Several of our sites have halted new enrollment at this time and we continue to monitor whether additional sites would need to be activated. Some patients may not be able to comply with clinical trial protocols, and data collected may be incomplete, if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations.

If patients are unwilling to participate in our clinical trials for any reason, including the existence of other approved therapies or concurrent clinical trials for similar patient populations, if they are unwilling to enroll in a clinical trial with a placebo-controlled design, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure you that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Our product candidates or any future product candidates may be associated with undesirable side effects or AEs that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As with most pharmaceutical products, use of our product candidates could be associated with side effects or AEs which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or a comparable foreign regulatory authority. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. Furthermore, certain of our product candidates, such as IDE196, may be co-administered with third-party approved or experimental therapies, such as binimetinib or crizotinib in the combination arms of our Phase 1/2 clinical trial. These combinations may have additional side effects. The uncertainty resulting from the use of our product candidates in combination with other therapies may make it difficult to accurately predict side effects in future clinical trials.

To date, only one of our product candidates, IDE196, has been tested in clinical trials, including an ongoing Phase 1 clinical trial and an ongoing Phase 1/2 clinical trial, and has been observed to be generally well tolerated, with the most common AEs reported being hypotension, GI toxicities, and fatigue. If unacceptable side effects arise in the further development of IDE196, including in combination with binimetinib or crizotinib, or in the development of any of our other product candidates, we, the FDA, or the IRBs at the institutions in which the clinical trials are being conducted could suspend or terminate our clinical trials or the FDA or a comparable foreign regulatory authority could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

In addition, even if we successfully advance our product candidates or any future product candidates into and through clinical trials, such trials will likely only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

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

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

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would adversely affect our business, financial condition, results of operations and prospects. In addition, if one or more of our product candidates prove to be unsafe, our entire technology platform and pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to successfully develop molecular diagnostics for biomarkers that enable patient selection and/or that demonstrate drug-target interaction, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates.

A key component of our strategy includes the use of molecular diagnostics to guide patient selection and/or to confirm target engagement of our product candidates. In some cases, a diagnostic may be commercially available, for example, on a tumor-profiling panel. If not already commercially available, we may collaborate with diagnostic companies for the development of biomarkers associated with our product candidates. We may have difficulty in establishing or maintaining such development relationships, and we will face competition from other companies in establishing these collaborations.

There are also several risks associated with biomarker identification and validation. We, in collaboration with any diagnostic partners, may not be able to identify predictive biomarkers or pharmacodynamic biomarkers for one or more of our programs. We may not be able to validate potential biomarkers (e.g., certain genetic mutations) or their functional relevance preclinically in relevant *in vitro* or *in vivo* models. Data analytics and information from databases that we rely on for identifying or validating some of our biomarker-target relationships may not accurately reflect potential patient populations. Potential biomarkers, even if validated preclinically, may not be functionally effective or validated in human clinical trials.

If we, in collaboration with these parties, are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected. The development of companion diagnostic products requires a significant investment of working capital, and may not result in any future income. This could require us to raise additional funds, which could dilute our current investors or impact our ability to continue our operations in the future.

There are also risks associated with diagnostics that are commercially available, including that we may not have access to reliable supply for such diagnostics.

The failure to obtain required regulatory approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of our product candidates. Moreover, the commercial success of any of our product candidates may be tied to the regulatory approval, market acceptance and continued availability of a companion diagnostic.

The FDA regulates *in vitro* companion diagnostics as medical devices that will likely be subject to and require prospective validation in clinical trials in conjunction with the clinical trials for our product candidates, and which will require regulatory clearance or approval prior to commercialization. We plan to collaborate with third parties for the development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. Our third-party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our product candidates. In addition, the commercial success of any of our product candidates may be tied to and dependent upon the receipt of required regulatory clearances or approvals of the companion diagnostic.

Even if a companion diagnostic is approved, we will rely on the continued ability of any third-party collaborator to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. Furthermore, if commercial tumor profiling panels are not able to be updated to include additional tumor-associated genes, or if clinical oncologists do not incorporate molecular or genetic sequencing into their clinical practice, we may not be successful in developing or commercializing our existing product candidates or any future product candidates.

Interim, "topline" and preliminary data from our clinical trials may differ materially from the final data.

From time to time, we may publicly disclose preliminary or "topline" data from our clinical trials, which are 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 results that we report may differ from future results of the same clinical trials, or different conclusions or considerations may qualify such topline 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 clinical trials. Interim data from clinical trials 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, financial condition, results of operations and prospects.

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 the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically a summary of extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline 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, financial condition, operating results and prospects.

We may be unable to obtain regulatory approval for our product candidates or any future product candidates. The denial or delay of such approval would prevent or delay commercialization of our product candidates and adversely impact our business, financial condition, operating results and prospects.

The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Neither we nor any collaborator, such as GSK or any future collaborator, is permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, that such product candidates are safe and effective for their intended uses. Foreign regulatory authorities may require a similar demonstration before we can obtain approval to commercialize a product candidate abroad. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or a comparable foreign regulatory authority can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials, or results may not meet the level of statistical significance required by the FDA or a comparable foreign regulatory agency for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we are unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the FDA’s or the applicable comparable foreign regulatory agency’s non-approval of the formulation, labeling or specifications of our product candidates or any of our future product candidates;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities could question the integrity of data obtained in our current or future clinical trials, for example, due to missed protocol procedures due to the impact of the COVID-19 pandemic;

- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- such authorities may only approve indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we or any of our collaborators, such as GSK or any potential future collaborators, contract for clinical and commercial supplies; and
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our collaborators' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our collaborators, such as GSK or any potential future collaborators, from commercializing any products.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The 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, financial condition, results of operations and prospects.

Even if we eventually complete clinical trials and receive approval of an NDA or foreign marketing application for a product, the FDA or a comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA or a comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or a comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

We may develop our product candidates and future product candidates in combination with other therapies, and safety or supply issues with combination-use products may delay or prevent development and approval of our product candidates.

We may develop our product candidates in combination with one or more cancer therapies, both approved and unapproved. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. Similarly, if the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or a similar regulatory authority outside of the United States. We may be unable to effectively identify and collaborate with third parties for the evaluation of our product candidates in combination with their therapies. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. The regulations prohibiting the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. In addition, there are additional risks similar to the ones described for our products currently in development and clinical trials that result from the fact that such cancer therapies are unapproved, such as the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or a similar regulatory authority outside of the United States does not approve these other drugs or revokes approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market such product.

A breakthrough therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will obtain marketing approval.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the clinical trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval. For some of our programs for which we intend to conduct basket trials, which will be designed to include multiple clinically defined populations under one investigational protocol though each population is enrolled and analyzed separately, we may not be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete.

The biotechnology and pharmaceutical industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or will likely develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of diseases and other conditions for which we may try to develop product candidates. Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. We believe that while our precision medicine target and biomarker discovery platform and our scientific and technical know-how give us a competitive advantage in this space, competition from many sources remains. Our competitors include larger and better funded biopharmaceutical, biotechnological and oncology therapeutics companies, as well as universities and other research institutions.

Our commercial opportunity and success will be reduced or eliminated if competing products emerge that are safer, more effective, or less expensive than the therapeutics we develop. Our competitors may develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Although we believe that IDE196 is currently the most advanced small molecule PKC inhibitor for genetically-defined cancers having GNAQ or GNA11 gene mutations in clinical trials, others may receive approval for competitive products before we do. If any of our product candidates are approved, they will compete with a range of therapeutic treatments that are either in development or currently marketed. For IDE196, our small molecule inhibitor targeting PKC in genetically-defined solid tumors having GNAQ or GNA11 mutations or other genetic alterations that activate the PKC signaling pathway, other companies are conducting research and development of potential therapies for metastatic uveal melanoma based on other targets and approaches. For example, Immunocore is developing IMCgp100 as monotherapy for metastatic uveal melanoma in a current Phase 2 clinical trial for patients with the HLA-A2 allele – which represents approximately 50% of metastatic uveal melanoma patients. For our pipeline of small molecule therapeutics based on synthetic lethality, potential competition includes established companies as well as earlier-stage emerging biotechnology companies. Multiple companies have been involved with research and development of PARP inhibitors, including AstraZeneca (Lynparza), Clovis (Rubraca), Tesaro (Zejula), and Pfizer (Talzenna). With respect to our MAT2A inhibitor for solid tumors having MTAP gene deletion, Agios is developing AG-270 in a Phase 1 clinical trial for certain advanced solid tumors or lymphoma. Additionally, several other early-stage companies, including Artios, Cyteir, KSQ, MetaboMed, NeoMed, Repare and Tango are performing research in synthetic lethality. Development decisions and data from clinical trials of our competitors may adversely impact clinical development of our product candidates, and may additionally or alternatively have a material adverse impact on our financial condition or business prospects.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and a gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

In some cases we may also develop diagnostics to enable relevant biomarker screening for clinical and commercial purposes in connection with our product candidates. If not already commercially available, we anticipate working in collaboration with diagnostic companies for this development, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, coverage, reimbursement and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competing products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

We expect to expand our development and regulatory capabilities and potentially implement sales and distribution capabilities, and as a result, we will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of September 30, 2020, we had 58 employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities, submit for regulatory approval and, if approved, commercialize our lead product candidate or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

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

There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facilities to accommodate such required expansion.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell any products effectively, if approved, or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize any product, if approved, in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In advance of any of our product candidates receiving regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time-consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. Under our GSK Collaboration Agreement, GSK will be responsible for commercialization of any MAT2A (if GSK exercises the Option and obtains HSR Clearance thereof), POLQ, or WRN products. We may choose to collaborate with additional third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

If we fail to attract and retain senior management and key scientific personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our President and Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of any products, initiation or completion of our planned clinical trials or the commercialization of our lead product candidate or any other product candidates.

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

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

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

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and any third-party manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts, commercialization efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We attempt to distribute our technology, biology, execution and financing risks across a range of therapeutic classes, disease states, programs and technologies. Due to the significant resources required for the development of our broad portfolio of programs, and depending on our ability to access capital, we must make certain risk assessments and prioritize development of certain product candidates. Moreover, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Our organization is committed to a broad approach to precision medicine that seeks to maximize our integrated biomarker and small molecule drug discovery capabilities. Our current portfolio consists of multiple programs, extending across multiple classes of precision medicine, including direct targeting of oncogenic pathways and synthetic lethality. Together, these programs require significant capital investment. The directly targeted therapy programs are at various stages of preclinical and early clinical development, and our synthetic lethality programs are in the target identification, validation and lead optimization stages of development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between advancing and expanding our synthetic lethality and direct targeting programs. Because we have limited financial and managerial resources, we focus on specific product candidates, indications and discovery programs. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Furthermore, as our programs progress, we or others may determine: that certain of our risk allocation decisions were incorrect or insufficient; that we made platform level technology mistakes; that individual programs or our approach to synthetic lethality or precision medicine in general has technology or biology risks that were unknown or underappreciated; that our choices on how to build our organizational infrastructure to drive our expansion will result in an inability to manufacture our products for clinical trials or otherwise impede our manufacturing capabilities; or that we have allocated resources in such a way that large investments are not recovered and capital allocation is not subject to rapid re-direction. All of these risks may relate to our current or future precision medicine programs or companion diagnostics, and in the event material decisions in any of these areas turn out to have been incorrect or under-optimized, we may experience a material adverse impact on our business, financial condition, results of operations and prospects.

The COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely affect our business and operations, including the pace of enrollment in current or future clinical trials.

Outbreaks of epidemic, pandemic, or contagious diseases, such as the current novel coronavirus or, historically, the Ebola virus, Middle East Respiratory Syndrome, Severe Acute Respiratory Syndrome, or the H1N1 virus, could disrupt our business. For example, beginning in late 2019, the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, has evolved into a global pandemic. On January 30, 2020, the World Health Organization declared the outbreak of COVID-19 a "Public Health Emergency of International Concern," and on March 11, 2020, the

World Health Organization characterized the outbreak as a “pandemic”. The governors of California and over forty other states, as well as mayors of many cities, ordered their residents to cease traveling to non-essential jobs and to curtail all unnecessary travel, and to stay in their homes as much as possible. As of late October 2020, the coronavirus has spread to most regions of the world and the United States continues to experience significant COVID-19 outbreaks, particularly in certain states, such as California. If the current economic conditions worsen or last for an extended period of time, we will be forced to significantly scale back our business and growth plans, which could have a material adverse effect on our business.

The COVID-19 pandemic is affecting the United States and global economies and may affect our operations and those of third parties on which we rely. Some of these third parties have experienced shut-downs, supply chain and experimental study interruptions or slow-downs, and more third parties could experience such shut-downs, interruptions or slow-downs. Individuals at our company or at such third parties could become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. In response to the COVID-19 pandemic, San Mateo County, California, in which our primary office resides, issued a “shelter in place” order in March 2020, which was issued in accordance with the March 2020 Proclamation of a State of Emergency issued by the Governor of California. We have closed our offices and requested that most of our personnel, including all of our administrative employees, work remotely, restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site and limited the number of staff in any given research and development laboratory. While the San Mateo County “shelter in place” order was rescinded on June 17, 2020 and replaced with a “reopening plan” order, we have continued to restrict our personnel as outlined above. The COVID-19 pandemic could disrupt our ability to secure supplies for our facilities and to provide personal protective equipment for our employees. The safety, health and well-being of our workforce is of primary concern and we may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the novel coronavirus. In addition, the COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. The evolving COVID-19 pandemic may also, directly or indirectly, impact the pace of enrollment in current or future clinical trials.

While the COVID-19 pandemic did not materially adversely affect our business operations in the quarter ended September 30, 2020, economic and health conditions in the United States and across most of the globe have changed rapidly since the end of the quarter and may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a continuing widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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

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

If a natural disaster, power outage or other event, such as the COVID-19 pandemic, occurred that prevented us from using all or a significant portion of our headquarters or other facilities, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, the third parties on which we depend, including suppliers, contract manufacturers and CROs are similarly vulnerable to natural disasters or other sudden, unforeseen and serious adverse events. If such an event were to affect our supply chain, manufacturing arrangements or interfere with a preclinical study or clinical trial, it could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

The commercial success of our partnered product candidates in our MAT2A (if GSK successfully exercises the Option and obtains HSR Clearance thereof), POLQ and WRN programs, which are part of the GSK Collaboration Agreement, will depend in large part on the development and marketing efforts of GSK. If GSK is unable to perform in accordance with the terms of the GSK Collaboration Agreement, our potential to generate future revenue from these programs would be significantly reduced and our business would be materially and adversely harmed.

We will have limited influence and/or control over GSK's approaches to development and commercialization of any MAT2A (if GSK exercises the Option and obtains HSR Clearance thereof), POLQ or WRN products. While we will have the right to receive potential milestone, profit share and royalty streams payable as GSK or its sublicensees advance development of such MAT2A, POLQ, or WRN products, we are likely to have limited ability to influence GSK's development and commercialization efforts. If GSK does not perform in the manner that we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization efforts related to product candidates we have licensed to GSK could be delayed or terminated. Furthermore, GSK or its licensees may elect to devote greater resources to other programs that do not relate to us or our collaboration.

If we terminate the GSK Collaboration Agreement, or any program thereunder due to a material breach by GSK, we have the right to assume the responsibility at our own expense for the development of the applicable product candidates. Assumption of sole responsibility for further development will greatly increase our expenditures, and may mean we need to limit the size and scope of one or more of our programs, seek additional funding and/or choose to stop work altogether on one or more of the affected product candidates. This could result in a limited potential to generate future revenue from such product candidates, and our business could be materially and adversely affected.

We rely on third parties to conduct certain of our preclinical studies and all of our clinical trials and intend to rely on third parties in the conduct of all of our future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, it may delay or prevent us from seeking or obtaining regulatory approval or commercializing our current or future product candidates.

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

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. Further, some of these agreements may also be terminated by such third parties on short notice, or under certain circumstances, including our insolvency. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements

with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, and our business, financial position, results of operations and prospects may be adversely affected.

We rely on third parties for the manufacture of our product candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture of any future approved products. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency compounds, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. These third-party manufacturers may be delayed in their manufacture or shipment of our product candidates due to the COVID-19 pandemic. Additionally, our ability to audit these third-party manufacturers for compliance with cGMP requirements and our specifications may be hindered or delayed due to the COVID-19 pandemic.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

In addition, we may be unable to establish or renew any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us, particularly if the COVID-19 pandemic continues or worsens.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

We rely on, and in the future may rely on, third-party databases and collaborations with third parties to inform patient selection and drug target identification for our existing product candidates and any future product candidates and for the supply of biomarker companion diagnostics.

We are using bioinformatics, including data analytics, biostatistics, and computational biology, to identify new target and biomarker opportunities. As part of this approach, we interrogate public and proprietary databases comprising human tumor genetic information and specific cancer-target dependency networks. We rely on these databases and data analytics for identifying or validating some of our biomarker-target relationships and access to these databases may not continue to be available publicly or through a proprietary subscription on acceptable terms.

Many of our precision medicine targeted therapeutic product candidates also rely on the availability and use of commercially available tumor diagnostics panels or data on the prevalence of our target patient population to inform the patient selection and drug target identification for our product candidates. In cases where such biomarker diagnostic is not already commercially available, we expect to establish strategic collaborations for the clinical supply and development of companion diagnostics. If these diagnostics are not able to be developed, or if commercial tumor profiling panels are not able to be updated to include additional tumor-associated genes, or if clinical oncologists do not incorporate molecular or genetic sequencing into their clinical practice, we may not be successful in developing our existing product candidates or any future product candidates.

We depend on third-party suppliers for key materials required for the production of our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business.

We rely on third-party suppliers for certain materials, such as starting reagents, required for the production of our product candidates and/or for certain materials and assays, such as diagnostics, for clinical and commercial use of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Additionally, the facilities to manufacture our product candidates must be the subject of a satisfactory inspection before the FDA or other regulatory authorities approve an NDA or grant a marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturing partners for compliance with the FDA's requirements for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's and other regulatory authorities' cGMP requirements, our product candidates will not be approved or, if already approved, may be subject to recalls.

Furthermore, certain of the third-party suppliers on which we rely are based in the PRC. The evolving trade dispute between the PRC and the United States has resulted in the imposition of significant tariffs on certain imports from the PRC. Any deterioration of the relationship between the United States and the PRC, or the imposition of more stringent export controls or tariffs applicable to our suppliers in the PRC, could adversely affect our ability to obtain the raw materials required for the manufacture of our product candidates, and therefore adversely affect our business, financial condition, results of operations and prospects.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer; and
- the possibility that we may not be able to secure a manufacturer or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs.

Any of these factors could cause the delay of approval or commercialization of any products, cause us to incur higher costs or prevent us from commercializing any products successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA or any other relevant regulatory authority.

If we fail to comply with our obligations under our license agreement with Novartis, we could lose license rights that are important to our business.

Our license agreement with Novartis provides that we must use commercially reasonable efforts to obtain regulatory approval for a product candidate using the licensed compound. The agreement further imposes an obligation to make various milestone payments and royalty payments as well as other obligations on us. If we materially breach the terms of the license agreement and fail to cure such breach within 90 days of being notified of the breach, then Novartis may terminate the license agreement. In addition, Novartis has the right to terminate on our insolvency. If the agreement is terminated, then we will not be able to further develop or commercialize, as the case may be, IDE196 or any future related product candidates.

Furthermore, any dispute with Novartis may result in the delay or termination of the research, development or commercialization of IDE196 or any future related product candidates, and may result in costly litigation or arbitration that diverts management attention and resources away from our day-to-day activities, which may adversely affect our business, financial condition, results of operations and prospects.

Our existing collaboration arrangements and any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates or diagnostics associated with such product candidates.

In the future, we may seek to enter into additional collaboration arrangements for the development or commercialization of certain of our product candidates or diagnostics for biomarkers associated with our product candidates. To the extent that we decide to enter into additional collaboration agreements in the future, we may face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts to prudently manage our existing collaborations or to enter new ones should we chose to do so. The terms of new collaborations or other arrangements that we may establish may not be favorable to us.

The success of our collaboration arrangements, including our GSK Collaboration Agreement, will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

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

Risks Related to Commercialization of Our Product Candidates

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

If one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

For example, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product candidate. The FDA may also require a 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, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including AEs 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:

- suspension or withdrawal of regulatory approval, restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or additional clinical trials;
- suspension of any of our ongoing clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of 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.

The occurrence of any event or penalty described above may inhibit our ability to commercialize any future approved product and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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. 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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump Administration may impact our business and industry. Namely, the Trump Administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant

burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

The incidence and prevalence of our target patient populations are estimations. If the market opportunities for our product candidates are smaller than we estimate, our business, financial position, results of operations and prospects may be harmed.

We rely on various sources, including published literature and public or proprietary databases, to ascertain an estimate of the number of patients having particular genetic alterations, such as mutations, deletions or fusions, across various tissue-type specific indications. The determinable prevalence may vary depending on the source and quality of the underlying data and in some cases, insufficient data or poorly curated data may impact our ability to accurately estimate the prevalence of our target patient populations for each indication and in the aggregate across multiple indications both in the clinical trial setting, as well as in the commercial setting, if our product is approved. If the market opportunities for our product candidates are smaller than we estimate, our business, financial position, results of operations and prospects may be harmed. In addition, upon treatment with our product candidates, patients may have or develop resistance to our product candidates, reducing the addressable patient population and the duration of treatment.

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

Even if our product candidates or any future product candidate receives FDA or other regulatory approvals, the commercial success of any product will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. For a variety of reasons, including among other things, competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of any products, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the availability of companion diagnostics for biomarkers associated with our product candidates or any other future product candidates;
- the time required for manufacture and release of our products;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for any of our products that may be approved;
- acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies for a particular indication;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payors, physicians and patients;
- the prevalence and severity of side effects;

- limitations or warnings contained in the FDA-approved labeling for our products;
- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our products as a solution;
- any FDA requirement for a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

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

The successful commercialization of any products will depend in part on the extent to which governmental authorities, private health insurers, managed care plans and other third-party payors provide coverage, adequate reimbursement levels and implement pricing policies favorable for any products. Failure to obtain or maintain coverage and adequate reimbursement for products, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers, managed care plans and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement by third-party payors for our products will have an effect on our ability to successfully commercialize our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. We cannot be sure that coverage will be available for any product that we may develop. A decision by a third-party payor not to cover any of our product candidates could reduce physician utilization of our products once approved and adversely affect our business, financial condition, results of operations and prospects.

Assuming there is coverage for our products, if any, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our products, pricing of other third-party therapeutics may limit the amount we will be able to charge for our products. These third-party payors may deny or revoke the reimbursement status of our products, if approved, or establish prices for our products at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available, is decreased or eliminated in the future, or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on our products.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products, if any. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

We face an inherent risk of product liability as a result of the planned clinical trials of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of any products. 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 any products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products.

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

Risks Related to Intellectual Property

Our success depends on our ability to obtain and maintain protection for our intellectual property and our proprietary technologies and to avoid infringing the rights of others.

Our commercial success depends in part on our ability to obtain and maintain patent, trade secret and other intellectual property protection for our product candidates and proprietary technologies as well as our ability to operate without infringing upon the proprietary rights of others.

We and our licensors have applied, and we intend to continue applying, for patents covering important aspects of our product candidates, proprietary technologies and their uses as we deem appropriate. However, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to apply for patents on certain aspects of our current or future product candidates and proprietary technologies in a timely fashion, at a reasonable cost, in all jurisdictions, or at all.

Our patent applications cannot be enforced against third parties practicing the inventions claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the invention as claimed. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators or licensors will be successful in protecting our product candidates and proprietary technologies by obtaining and defending patents. These risks and uncertainties include the following:

- the United States Patent Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other requirements during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained or licensed patents that will limit, interfere with or eliminate our ability to make, use and sell our product candidates;
- other parties may have designed or may design around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any product candidates that we may develop;
- because 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 or our licensors were the first to file any patent application related to our product candidates and proprietary technologies;
- 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 for any application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. And although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action or similar proceedings in court or before patent offices in the United States or foreign jurisdictions for a given period after allowance or grant, during which time third parties can raise objections against such patents. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates, or limit the duration of the patent protection of our product candidates.

The degree of future protection for our patent rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- any of the patents we own or license will be found to ultimately be valid and enforceable if subject to challenge;
- any patents issued to us or our licensors will provide a basis for an exclusive market for any commercially viable products we may develop or will provide us with any competitive advantages;
- we will develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- our commercial activities will not infringe upon the patents of others.

Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our competitive position, business, financial condition, results of operations and prospects.

Furthermore, our owned and in-licensed intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations, and prospects.

If we fail to obtain sufficient patent or other intellectual property protection for our product candidates or proprietary technologies or if we lose any patent or other intellectual property protection for our product candidates or proprietary technologies, our business, financial condition, results of operations and prospects could be adversely affected.

If we do not obtain patent term extension for patents covering our product candidates, our business may be materially harmed, and in any case, the terms of our patents may not be sufficient to effectively protect our product candidates and business.

Patents have a limited term. In most countries, including the United States, the expiration of a patent is generally 20 years after its first effective non-provisional filing date. However, depending upon the timing, duration and specifics of FDA marketing approval of IDE196, our other product candidates or any future product candidates, one or more of any U.S. patents we may be issued or have licensed may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments.

The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our competitive position, business, financial condition, results of operations, and prospects could be harmed, possibly materially.

If there are delays in obtaining regulatory approvals or other additional delays, the period of time during which we can market our product candidates under patent protection could be further reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. Once the patent term has expired, we may be open to competition from similar or generic products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our product candidates may be dependent on our licensors.

We currently are reliant upon licenses of certain intellectual property rights and proprietary technology from third parties that are important or necessary to the development of our proprietary technology, including technology related to our product candidates. For example, we rely on our exclusive license agreement with Novartis for the clinical development of IDE196 and our option and license agreement with Cancer Research UK for the clinical development of PARG inhibitors. These licenses, and other licenses we may enter into in the future, may not provide adequate rights to use such intellectual property rights and proprietary technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could harm our business, financial condition, results of operations and prospects significantly.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Our current licenses impose, and our future licenses likely will impose, various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, we may be subject to liability, including the payment of damages, and the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from developing and commercializing our product candidates and proprietary technologies. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products similar or identical to our planned products. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor’s rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize product candidates, we may be unable to achieve or maintain profitability. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property rights that are subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may fail to comply with any of our obligations under existing or future agreements pursuant to which we license or have otherwise acquired intellectual property rights or technology, which could result in the loss of rights or technology that are material to our business.

We are party to various agreements that we depend on to operate our business, including intellectual property rights relating to IDE196, in particular, our agreement with Novartis. Our rights to use currently licensed intellectual property, or intellectual property to be licensed in the future, are or will be subject to the continuation of and our compliance with the terms of these agreements. These agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations which could lead to disputes, including but not limited to those regarding:

- the scope of rights granted under the license agreement;
- the extent to which our proprietary technology and product candidates infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us or our counterparties, alone or jointly;
- the scope and duration of our payment obligations;
- rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

The resolution of any contractual interpretation dispute that may arise, if unfavorable to us, could have a material adverse effect on our business, financial condition, results of operations and prospects. Such resolution could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement or decrease the third party's financial or other obligations under the relevant agreement.

Furthermore, if disputes over intellectual property rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under current or future license agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

Third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products.

Our commercial success depends significantly on our ability to operate without infringing the intellectual property rights of third parties. However, our research, development and commercialization activities may nonetheless be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Claims by third parties that we infringe their intellectual property rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. We cannot assure you that our operations do not, or will not in the future, be found to infringe existing or future patents.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates or impair our competitive position. As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, *inter partes* review proceedings and post-grant review proceedings before the USPTO

and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. For example, we are aware of an international patent application published as PCT WO 2017/096165 A1. If a patent issues from such patent application with claims similar to those published, our ability to commercialize a product candidate for our MAT2A program may be adversely affected if we do not obtain a license under such patent.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our analysis of these issues, including interpretation the relevance or the scope of claims in a patent or a pending application, determining applicability of such claims to our proprietary technologies or product candidates, predicting whether a third party's pending patent application will issue with claims of relevant scope, and determining the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties.

Additionally, patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. As a result, we may be unaware of third-party patents that may be infringed by commercialization of IDE196 or our other product candidates, and cannot be certain that we were the first to file a patent application related to a product candidate or proprietary technology. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims.

Although no third party has asserted a claim of patent infringement against us as of September 30, 2020, others may hold proprietary rights that could prevent IDE196, our other product candidates or any future product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or proprietary technologies could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe or attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing, and require us to obtain a license to manufacture or market IDE196, our other product candidates or any future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be time-consuming and a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. In addition, we cannot be certain that we could redesign our product candidates or proprietary technologies to avoid infringement, if necessary, or on a cost-effective basis. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing IDE196, our other product candidates or any future product candidates, until the asserted patent expires or is held finally invalid or not infringed in a court of law. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity or the disclosure of confidential information, and the perceived value of our product candidates or intellectual property could be diminished correspondingly.

Additionally, our collaborators, such as GSK or any third parties with which we collaborate in the future, may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court or administrative tribunal may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our collaborators, such as GSK or potential future collaborators, were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent agencies. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and could result in the revocation, cancellation, or amendment of our patents or those of our licensors. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on an affected product candidate. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Additionally, interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO, or equivalent actions brought in foreign jurisdictions, may be necessary to determine the priority of invention with respect to our patents or patent applications or those of our licensors. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. An unfavorable outcome could require us to cease using the covered technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. These and other uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

We may be subject to claims that we have wrongfully hired an employee, consultant, advisor or other third party from a competitor or that we or our employees, consultants, advisors or other third parties have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and biopharmaceutical industries, in addition to our employees, we engage the services of consultants, advisors and other third parties to assist us in the development of our product candidates. Many of these individuals, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or biopharmaceutical companies including our competitors or potential competitors. Although we try to ensure that individuals working for or collaborating with us do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that we, our employees, consultants, advisors or other third parties inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants advisors or other third parties, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our competitive position, business, financial condition, results of operations, and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

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

Our agreements with employees and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all such individuals complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be self-executing and despite such agreement, such inventions may become assigned to third parties. 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. We may be subject to claims that former employees, consultants, advisors or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, consultants, advisors or other third parties obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information. We have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants, advisors and appropriate third parties. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant, advisor or other third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position, business, financial condition, results of operations, and prospects would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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. For example:

- others may be able to make precision medicines that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators 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 or future collaborators 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;
- our competitors might conduct research and development activities 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; and
- we may not develop additional proprietary technologies that are patentable;

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Government Regulation

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

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- an increase to the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and an extension the rebate program to individuals enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% 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;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, which includes a provision that entered into effect on January 1, 2019, that repeals the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is 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 ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA 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. It is unclear how these decisions, subsequent appeals, if any, or other efforts to challenge, repeal or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Trump Administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented 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. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, 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 any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- the Federal Food Drug or Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- similar healthcare and data protection laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We face regulation and potential liability related to the privacy, data protection and information security which may require significant resources and may adversely affect our business, operations and financial performance.

The regulatory environment surrounding information security, data collection and privacy is increasingly demanding. We are subject to numerous U.S. federal and state laws and non-U.S. regulations governing the protection of personal and confidential information of our clinical patients, clinical investigators, employees and vendors/business contacts, including in relation to medical records, credit card data and financial information. For example, on May 25, 2018, the GDPR became effective, implementing more stringent requirements in relation to our use of personal data. The GDPR repeals the Data Protection Directive (95/46/EC) and is directly applicable in all E.U. member states and will also remain law in the United Kingdom until the end of the transition period on December 31, 2020 provided for in the Withdrawal Agreement between the EU and the U.K. The GDPR significantly increased fines to up to 4% total worldwide annual turnover or up to €20 million (whichever is higher) for non-compliance with its requirements. We will be subject to the GDPR where we have an E.U. presence or "establishment", when conducting clinical trials with E.U. based data subjects (whether the trials are conducted directly by us or through a clinical vendor or collaborator) or when offering approved products or services in the future to E.U. based data subjects. After the end of the transition period on December 31, 2020, a similar data protection regime will apply in the United Kingdom.

The GDPR sets out a number of requirements that must be complied with when handling the personal data of such E.U. based data subjects including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; the new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual (even, in certain situations, where such data is key coded) are all classified as "special category" data under GDPR and afford greater protection and require additional compliance obligations. Further, E.U. member states have a broad right to impose additional conditions – including restrictions – on these data categories. This is because the GDPR allows E.U. member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As the E.U. member states reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant E.U. member states' laws and regulations, including where permitted derogations from the GDPR are introduced.

The introduction of the GDPR, and any resultant changes in E.U. member states' national laws and regulations, will increase our compliance obligations and will necessitate the review and implementation of policies and processes relating to our collection and use of data. This increase in compliance obligations could also lead to an increase in compliance costs which may have an adverse impact on our business, financial condition or results of operations.

In the United States, HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. 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 constitutes 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. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain states govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act, or CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. 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. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

If any person, including any of our employees, clinical trial collaborators or those with whom we share such information, negligently disregards or intentionally breaches our established controls with respect to clinical subject, clinical investigator or employee data, or otherwise mismanages or misappropriates that data, we could be subject to significant monetary damages, regulatory enforcement actions, fines and/or criminal prosecution in one or more jurisdictions. In addition, a data breach could result in negative publicity which could damage our reputation and have an adverse effect on our business, financial condition or results of operations.

Risks Related to Our Common Stock

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

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this Quarterly Report on Form 10-Q and others such as:

- results from, and any delays in, our clinical trials for IDE196, or any other future clinical development programs, including public misperception of the results of our clinical trials;
- announcements by academic or other third parties challenging the fundamental premises underlying our approach to treating cancer and/or biopharmaceutical product development;
- announcements of regulatory approval or disapproval of our current or any future product candidates;
- failure or discontinuation of any of our research and development programs;
- manufacturing setbacks or delays of or issues with the supply of the materials for our product candidates;
- announcements relating to or results from our GSK Collaboration Agreement;
- announcements relating to future licensing, collaboration or development agreements;
- delays in the commercialization of our current or any future product candidates;
- public misperception regarding the use of our therapies;
- acquisitions and sales of new products, technologies or businesses;
- quarterly variations in our results of operations or those of our future competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- major changes in our board of directors or management;
- new legislation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or comparable foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the biopharmaceutical and biotechnology sectors, particularly as a result of the volatility in the market caused by the COVID-19 pandemic; and
- general economic conditions in the United States and abroad.

In addition, the stock markets in general, and the markets for biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility, particularly in response to the COVID-19 pandemic. In particular, the market prices of securities of smaller biotechnology have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

An active, liquid and orderly market for our common stock may not be maintained, and you may not be able to resell your common stock.

Prior to our initial public offering, or IPO, in May 2019, there was no public market for shares of our common stock. Our stock recently began trading on the Nasdaq Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market on the Nasdaq Global Select Market or any other exchange in the future. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of September 30, 2020, we have outstanding a total of 29.1 million shares of common stock, of which the holders of approximately 5.0 million shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. In addition, as of September 30, 2020, approximately 4.0 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity incentive plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

General Risks

We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data or financial assets, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

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

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the pervasive use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property, including both our own and that of third parties. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, financial condition, results of operations and prospects.

If we engage in future acquisitions or strategic collaborations, it may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption or incurrence of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Our programs may require the use of intellectual property rights held by third parties to which we do not have rights. In such a case, the growth of our business will depend in part on our ability to acquire, in-license or use these rights. However, we may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates on reasonable terms and conditions or at all.

The acquisition or licensing of intellectual property rights for pharmaceutical products is very competitive. If we seek to acquire or license additional intellectual property rights, we may face substantial competition from a number of more established companies, some of which have acknowledged strategies to license or acquire products, and many of which have more institutional experience and greater financial and other resources than we have. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities, as may other emerging companies taking similar or different approaches to product licenses and/or acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines, which may provide those companies with an even greater competitive advantage. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us or may interfere with our acquisition or licensing of rights from others. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We have collaborated with U.S. academic institutions and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have on reasonable terms, we may have to abandon development of that program and our competitive position, business, financial condition, results of operations, and prospects could suffer.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Our patent rights may be affected by developments or uncertainty in the United States' or other jurisdictions' patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of other jurisdictions' patent offices.

There are a number of recent changes to U.S. patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application is typically entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the

USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. In addition, the U.S. congress may pass additional patent reform legislation that is unfavorable to us.

The 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 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 the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

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

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

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

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

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

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

As a public company, we are subject to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our audited financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on CROs and contract manufacturing organizations, or CMOs, to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Market or other adverse consequences that would materially harm to our business.

If we are unable to maintain effective internal controls, our business, financial position, results of operations and prospects could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Exchange Act, including Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting. However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an emerging growth company if we continue to take advantage of the exemptions available to us through the JOBS Act.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position, and results of operations.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate losses for U.S. federal income tax purposes, unused losses will carry forward to offset a portion of future taxable income, if any, until such unused losses expire, if ever. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change taxable income or tax liability may be limited. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOLs or credits if we undergo a future ownership change. We have experienced ownership changes in the past, and we may experience ownership changes in the future and/or subsequent shifts in our stock ownership (some of which may be outside our control). 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.

Enacted on June 29, 2020, California's Assembly Bill No. 85 generally prohibits the total amount of refunds or credit offsets that would otherwise be allowed for a taxable year beginning on or after January 1, 2020, and before January 1, 2023, from exceeding $5,000,000. This bill would, subject to certain exceptions related to a taxpayer's income, disallow a net operating loss deduction for any taxable year beginning on or after January 1, 2020, and before January 1, 2023, and would extend the carryover period for a net operating loss deduction disallowed by that provision, as specified. It is possible that these provisions could adversely affect our ability to utilize our net operating losses and business credits.

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

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

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

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

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

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

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

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

The cost of D&O insurance policy premiums is expected to continue to increase. If the costs of maintaining adequate D&O insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current D&O insurance coverage should become unavailable to us or become economically impractical, we may need to decrease our coverage limits or increase our self-insured retention or we may be unable to renew such insurance at all. If we incur liabilities that exceed our coverage or incur liabilities not covered by our insurance, we would have to self-fund any indemnification amounts owed to our directors and officers and employees in which case our results of operations and financial condition could be materially adversely affected. Additionally, a lack of D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business.

Our amended and restated certificate of incorporation provides for an exclusive forum in the Court of Chancery of the State of Delaware and in the U.S. federal district courts for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any state law 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, any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim.

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

We do not intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from the Sale of Registered Securities

Pursuant to a registration statement on Form S-1 (File No. 333-231081), as amended, which was declared effective by the SEC on May 22, 2019, we registered common stock to be sold in our IPO, in which we sold and issued 5,750,000 shares of common stock at a price to the public of $10.00 per share, which includes the full exercise of the underwriters' over-allotment option to purchase an additional 750,000 shares of common stock. We received aggregate gross proceeds of $57.5 million, or aggregate net proceeds of $50.2 million, after underwriting discounts, commissions and other offering costs. As of September 30, 2020, we have used all of the net proceeds from our IPO.

Issuer Purchases of Equity Securities

The following table summarizes repurchases of our common stock during the third quarter of fiscal 2020:

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet be Repurchased Under the Plans or Programs
July 1, 2020 to July 31, 2020	—	$ —	—	$ —
August 1, 2020 to August 31, 2020	5,349	1.23	—	—
September 1, 2020 to September 30, 2020	—	—	—	—
Total	5,349	$ 1.23	—	$ —

All of the shares repurchased, as reflected in the table above, were repurchases of unvested shares of our common stock that had been issued upon early exercise of stock options. Upon termination of employment of a person holding unvested shares, we are entitled to repurchase the unvested shares.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	5/28/2019	3.1	
3.2	Amended and Restated Bylaws.	8-K	5/28/2019	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	5/13/2019	4.2	
10.1†	Amendment No. 1 to Clinical Trial Collaboration and Supply Agreement between Pfizer Inc. and IDEAYA Biosciences, Inc. dated as of September 23, 2020.				X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
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	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

† Certain information in this exhibit has been excluded pursuant to Regulation S-K, Item 601(b)(10).

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

SIGNATURES

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

IDEAYA Biosciences, Inc.

Date: November 12, 2020

By: /s/ Yujiro Hata

Yujiro Hata
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2020

By: /s/ Paul Stone, J.D.

Paul Stone, J.D.
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

Amendment No. 1 to Agreement
("Amendment No. 1")

Amendment No. 1 Date:	September 23, 2020
Name of Original Agreement:	Clinical Trial Collaboration and Supply Agreement (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Effective Date of Original Agreement:	March 11, 2020
Parties:	Pfizer Inc. ("Pfizer") and Ideaya Biosciences, Inc. ("Ideaya")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement including certain definitions in the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. Defined Terms. Capitalized terms used but not defined herein shall have the respective meanings ascribed to such terms in the Agreement.

2. Amendment(s) to the Agreement.

2.1. The definition of "Pfizer Compound" is revised to read, in its entirety, as follows:

"1.42 **"Pfizer Compound"** means MEKTOVI (binimetinib) or a salt thereof, excluding, however, any generic version of binimetinib other than a generic version owned or controlled by Pfizer or its Affiliate and/or Xalkori (crizotinib)) or a salt thereof, excluding, however, any generic version of crizotinib other than a generic version owned or controlled by Pfizer or its Affiliate, as applicable."

2.2. The definition of "Study" is revised to read, in its entirety, as follows:

"1.55 "**Study**" means the portion of the Global Phase 1 study in Metastatic Uveal Melanoma (MUM) and GNAQ/11-mutated Solid Tumors (non-MUM) pertaining to the clinical evaluation of the Ideaya Compound in combination with either or both of the Pfizer Compounds."

2.3. The definition of "ALK Inhibitor" is added as new Section 1.59, as follows:

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

"1.59 "**ALK Inhibitor**" means any small or large molecule that inhibits the anaplastic lymphoma kinase enzyme (ALK)."

2.4. Section 3.8 of the Agreement is revised to read, in its entirety, as follows:

"3.8 All Clinical Data, including raw data and results therein, generated under this Agreement shall be jointly owned by Pfizer and Ideaya. It is understood and acknowledged by the Parties that positive Clinical Data could be used to obtain Regulatory Approvals or label changes for the Compounds. In such event, the Parties will enter into good faith negotiations to determine a regulatory submission strategy for the Compounds. Similarly, if either Party believes that reference to data from other studies of the other Party is necessary for such Party to obtain Regulatory Approvals or label changes for its Compound, the Parties will discuss in good faith appropriate terms for possible access to or right to reference such data for such purpose. Except as explicitly provided in Sections 9.1 and 9.2, Ideaya covenants not to disclose any unpublished Clinical Data or other documentation prepared specifically for use in connection with the Study to any Third Party in connection with Ideaya's independent research, development and/or commercialization of the Ideaya Compound in combination with Ideaya's or its Affiliate's or any Third Party's MEK Inhibitor or ALK Inhibitor, and Pfizer covenants not to disclose any unpublished Clinical Data or other documentation prepared specifically for use in connection with the Study to any Third Party in connection with Pfizer's independent research, development and/or commercialization of a Pfizer Compound in combination with Pfizer's or its Affiliate's or any Third Party's PKC Inhibitor."

2.5. Section 3.11 of the Agreement is revised to read, in its entirety, as follows:

"3.11 Notwithstanding anything in this Agreement to the contrary, each Party acknowledges and agrees that the other Party may have present or future business activities or opportunities, including business activities or opportunities with Third Parties, involving MEK Inhibitors or ALK Inhibitors, in the case of Ideaya, or PKC Inhibitors, in the case of Pfizer, or other similar products, programs, technologies or processes. Accordingly, each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, including MEK Inhibitors, ALK Inhibitors or PKC Inhibitors, provided that the Clinical Data, Sample Testing Results, Jointly Owned Inventions, and Confidential Information are not used or disclosed in connection therewith in violation of this Agreement."

2.6. Section 10.1.4 of the Agreement is revised to read, in its entirety, as follows:

"10.1.4 Pfizer shall have the first right to initiate legal action to enforce all Joint Patents against infringement, and to protect all Jointly Owned Inventions from misappropriation, by any Third Party where such infringement or misappropriation results

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

from the development or sale of a MEK Inhibitor or ALK Inhibitor or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that Pfizer fails to initiate or defend such action within [***] days after being first notified of such infringement or misappropriation, Ideaya shall have the right to do so at its sole expense. Similarly, Ideaya shall have the first right to initiate legal action to enforce all Joint Patents against infringement and to protect all Jointly Owned Inventions from misappropriation, by any Third Party where such infringement or misappropriation results from the development or sale of a PKC Inhibitor or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that Ideaya fails to initiate or defend such action within [***] days after being first notified of such infringement, Pfizer shall have the right to do so at its sole expense. In the event that legal action to enforce Joint Patents will involve infringement or misappropriation resulting from the development or sale of a molecule or molecules that is/are or include(s) both a MEK Inhibitor and a PKC Inhibitor or an ALK Inhibitor and a PKC Inhibitor, the Parties shall work together to coordinate such action and shall, unless one Party elects not to pursue such legal action, share the costs and expenses of such litigation equally. For clarity, if the alleged infringer is selling or intending to sell only one of a MEK Inhibitor, ALK Inhibitor or a PKC Inhibitor, then the foregoing obligation to share the costs and expenses of such litigation shall not apply."

2.7. Section 10.2 of the Agreement is revised to read, in its entirety, as follows:

"10.2 Inventions Owned by Pfizer. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating solely to the Pfizer Compound, a MEK Inhibitor or an ALK Inhibitor are the exclusive property of Pfizer. Pfizer shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention. For the avoidance of doubt, any Invention generically encompassing the Pfizer Compound (and not any Ideaya proprietary compound including the Ideaya Compound) within its scope, even where the Pfizer Compound is not disclosed per se, is the exclusive property of Pfizer."

2.8. Appendix A of the Agreement is revised to read, in its entirety, as set forthing in Appendix A of this Amendment No 1.

2.9. Appendix B of the Agreement is revised to read, in its entirety, as set forthing in Appendix B of this Amendment No 1.

3. Ratification of the Agreement. Except as expressly set forth in Article 2 above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 1 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

4. Counterparts. This Amendment No. 1 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

SIGNATURES IMMEDIATELY FOLLOWING ON NEXT PAGE

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

IN WITNESS WHEREOF, the duly authorized representatives of Pfizer and Ideaya have executed this Amendment No. 1 as of the date first above written.

Ideaya Biosciences, Inc.		**Pfizer Inc.**	
By:	/s/ Yujiro Hata	By:	/s/ Chris Boshoff
Print Name:	Yujiro Hata	Print Name:	Chris Boshoff
Title:	President and Chief Executive Officer	Title:	SVP & Chief Development Officer
Date:	9/23/2020 (Duly authorized)	Date:	9/23/2020 (Duly authorized)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Appendix A

PROTOCOL SUMMARY

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Appendix B– Supply Schedule

Supply of Compounds – Phase I/II Study combo with IDE196

Ideaya and **Pfizer** are entering into this Supply Schedule to define each Party's clinical supply chain responsibilities with respect to the IDEYA Study pursuant to the Clinical Trial Collaboration and Supply Agreement dated March 11, 2020, as amended by Amendment No. 1 to Agreement dated September 23, 2020.

This Supply Schedule is to be used for contracting purposes between **Ideaya** and **Pfizer** and defines the responsibilities not covered in the Quality Agreement for the binimetinib Drug Product ("Binimetinib Compound") and the crizotinib Drug Product ("Crizotinib Compound" and each a "Pfizer Compound"), clinical packaging/labeling, release, storage/distribution /control/disposal, import/export, and Interactive Response Technology (IRT), regulatory, forecast planning activities for the **Ideaya** Compound(s)/ binimetinib or Compound(s)/crizotinib and Ideaya combination clinical trials.

Upon approval, it will serve as the standard of operation between both parties for these clinical supply activities.

Ideaya will provide Pfizer written orders [***] days before delivery of the binimetinib Drug Product. Pfizer will provide Ideaya with binimetinib [***]. Pfizer is providing [***].

Ideaya will provide Pfizer written orders [***] days before delivery of the crizotinib Drug Product. Pfizer will provide Ideaya with [***].

Delivery timelines and Compound quantities are based on the Phase I/II study plan in place at the time of the Effective Date. Compound quantities are subject to modification based on Study conduct (due, for example, to the addition of Study sites or countries, patients with durable responses, etc). If the quantity of compounds set forth in this Agreement are not sufficient to complete the Study, Ideaya shall so notify Pfizer and the Parties shall discuss in good faith regarding additional quantities of Compounds to be provided and the schedule on which such additional quantities may be provided.

As specified in the Collaboration Agreement, the Parties agree that Pfizer shall provide each Pfizer Compound for use in the Study at no cost to Ideaya.

Following are estimates of the demand for the supply of the Pfizer Compound for the Study. The supply chain teams from Pfizer and Ideaya will meet regularly to review demand and supply requirements and adjust the delivery schedule to ensure continuous supply for the Study.

Study Assumptions

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

The source of the Compounds to be provided by the Parties during the Term may change. In such event, the supplying Party will ensure that all Compounds supplied by such Party will be from an approved source and the table above will be updated as applicable Regulatory Authorities approve the change to the Manufacturing Site.

The responsibilities of both parties are summarised in table below:

CLINICAL SUPPLIES TABLE OF ROLES AND RESPONSIBILITIES

Documentation will be transferred between the Clinical Supply Chain contacts or designee.

[***]

This Supply Schedule is binding on the final date of approval. The Supply Schedule can be reviewed at any time by mutual consent of each party to determine if changes will be considered minor or major. Any minor changes to the content of the Supply Schedule will be documented in the Revision History box and no re-routing for signatures will be required. A major change will necessitate the document to be revised, re-routed for signatures and be assigned the next sequential version number.

IN WITNESS HEREOF, Ideaya and Pfizer hereby approves this Supply Schedule, Version 1 as of the dates set forth below:

Ideaya Biosciences, Inc.		**Pfizer, Inc.**	
Signature	/s/ Yujiro Hata	Signature	/s/ Patrick Furcolo
Name	Yujiro Hata	Name	Patrick Furcolo
Title	President and Chief Executive Officer	Title	Director SupChainProjMgmt
Date	9/23/20	Date	9/23/20

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yujiro Hata, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of IDEAYA Biosciences, Inc.;

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

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

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

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

   (b) [omitted];

   (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: November 12, 2020

By: /s/ Yujiro Hata

Yujiro Hata
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Stone, J.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of IDEAYA Biosciences, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) [omitted];

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

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

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

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

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

Date: November 12, 2020

By: /s/ Paul Stone, J.D.

Paul Stone, J.D.
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting 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

I, Yujiro Hata, President and Chief Executive Officer of IDEAYA Biosciences, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2020 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: November 12, 2020

By: /s/ Yujiro Hata
Yujiro Hata
President and Chief Executive Officer
(Principal Executive Officer)

I, Paul Stone, J.D., Chief Financial Officer and General Counsel of IDEAYA Biosciences, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2020 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: November 12, 2020

By: /s/ Paul Stone, J.D.
Paul Stone, J.D.
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)