

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

OR

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

**For the transition period from to
Commission File Number: 001-39045**

IGM Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
**(State or other jurisdiction of
incorporation or organization)**
325 E. Middlefield Road
Mountain View, CA
(Address of principal executive offices)

77-0349194
**(I.R.S. Employer
Identification No.)**

94043
(Zip Code)

Registrant's telephone number, including area code: (650) 965-7873

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	IGMS	The Nasdaq Global Select Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 1, 2019, the registrant had 24,104,694 shares of common stock, \$0.01 par value per share, and 6,431,205 shares of non-voting common stock, \$0.01 par value per share, outstanding.

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Special Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and 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 “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” or “would,” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about: the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our discovery programs; our ability to utilize our IgM antibody platform to generate and advance additional product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals; our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that may enroll in our clinical trials; the commercializing of our product candidates, if approved; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; future strategic arrangements and/or collaborations and the potential benefits of such arrangements; our anticipated use of our existing resources and the proceeds from this offering; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash, cash equivalents and investments to fund our future operating expenses and capital expenditure requirements; our ability to retain the continued service of our key personnel and to identify, hire and retain additional qualified professionals; the implementation of our business model, strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our IgM platform, product candidates and discovery programs; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the pricing, coverage and reimbursement of our product candidates, if approved; developments relating to our competitors and our industry, including competing product candidates and therapies; and the ability of our clinical trials to demonstrate the safety and efficacy of our product candidates, and other positive results;

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects, and these forward-looking statements are not guarantees of future performance or development. 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 in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, 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 be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Quarterly Report on Form 10-Q, whether as a result of any new information, future events, or otherwise.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

IGM Biosciences, Inc.
Condensed Balance Sheets
(Unaudited)

(in thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 193,679	\$ 1,887
Short-term investments	48,396	—
Prepaid expenses and other current assets	6,005	485
Income tax receivable	35	35
Total current assets	248,115	2,407
Property and equipment, net	2,585	1,472
Long-term investments	9,274	—
Operating lease right-of-use asset	9,882	—
Restricted cash	—	100
Total assets	\$ 269,856	\$ 3,979
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	2,778	164
Accrued liabilities	2,082	3,582
Lease liabilities, current	1,564	—
Deferred rent	—	108
Related party loan	—	5,027
Other current liabilities	—	9
Total current liabilities	6,424	8,890
Lease liabilities, non-current	8,810	—
Total liabilities	15,234	8,890
Commitments and contingencies (Note 9)		
Convertible preferred stock, \$0.01 par value; 0 shares authorized as of September 30, 2019 and 9,501,624 shares authorized as of December 31, 2018; 0 shares issued and outstanding as of September 30, 2019 and 9,501,620 issued and outstanding as of December 31, 2018; liquidation value of \$0 as of September 30, 2019 and \$61,466 as of December 31, 2018	—	60,917
Stockholder's (deficit) equity;		
Preferred stock, \$0.01 par value; 200,000,000 shares authorized as of September 30, 2019 and 0 shares authorized as of December 31, 2018; 0 shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.01 par value; 1,000,000,000 shares authorized as of September 30, 2019 and 30,264,511 shares authorized as of December 31, 2018; 24,046,435 and 438,074 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	240	4
Non-voting common stock, \$0.01 par value; 6,431,208 shares authorized as of September 30, 2019 and 0 shares authorized as of December 31, 2018; 6,431,205 shares issued and outstanding as of September 30, 2019 and 0 shares issued and outstanding as of December 31, 2018	64	—
Additional paid-in-capital	346,679	751
Due from related party	—	(2,511)
Accumulated other comprehensive income	29	—
Accumulated deficit	(92,390)	(64,072)
Total stockholders' equity (deficit)	254,622	(65,828)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 269,856	\$ 3,979

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

IGM Biosciences, Inc.
Condensed Statements of Operations
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 8,279	\$ 5,172	\$ 22,494	\$ 11,148
General and administrative	2,394	1,373	6,067	2,597
Total operating expenses	10,673	6,545	28,561	13,745
Loss from operations	(10,673)	(6,545)	(28,561)	(13,745)
Other income, net	501	28	243	87
Net loss	\$ (10,172)	\$ (6,517)	\$ (28,318)	\$ (13,658)
Net loss per share, basic and diluted	\$ (2.41)	\$ (14.88)	\$ (16.13)	\$ (31.18)
Weighted-average common shares outstanding, basic and diluted	4,222,259	438,074	1,755,526	438,074

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

IGM Biosciences, Inc.
Condensed Statements of Comprehensive Loss
(Unaudited)
(in thousands)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Net loss	\$ (10,172)	\$ (6,517)	\$ (28,318)	\$ (13,658)
Other comprehensive income:				
Unrealized gain on investments	29	—	29	—
Comprehensive loss	<u>\$ (10,143)</u>	<u>\$ (6,517)</u>	<u>\$ (28,289)</u>	<u>\$ (13,658)</u>

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

IGM Biosciences, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Non-Voting Common Stock		Additional Paid-In-Capital	Due To (From) Related Party	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Share	Amount	Share	Amount	Share	Amount					
Balance—December 31, 2018	9,501,620	\$ 60,917	438,074	\$ 4	—	—	\$ 751	\$ (2,511)	\$ —	\$ (64,072)	\$ (65,828)
Exercise of stock options	—	—	7,566	—	—	—	10	—	—	—	10
Capital contribution from related party	—	—	—	—	—	—	23	—	—	—	23
Stock-based compensation expense	—	—	—	—	—	—	139	—	—	—	139
Net loss	—	—	—	—	—	—	—	—	—	(7,470)	(7,470)
Balance—March 31, 2019	9,501,620	60,917	445,640	4	—	—	923	(2,511)	—	(71,542)	(73,126)
Exercise of stock options	—	—	165,656	2	—	—	152	—	—	—	154
Issuance of common stock	—	—	7,565	—	—	—	11	—	—	—	11
Related party equity transaction	—	—	—	—	—	—	16	2,511	—	—	2,527
Issuance of Series C convertible preferred stock, net of											
issuance costs of \$0.1 million	4,690,997	61,868	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	141	—	—	—	141
Net loss	—	—	—	—	—	—	—	—	—	(10,676)	(10,676)
Balance—June 30, 2019	14,192,617	122,785	618,861	6	—	—	1,243	—	—	(82,218)	(80,969)
Exercise of stock options	—	—	3,329	—	—	—	5	—	—	—	5
Issuance of Series C convertible preferred stock, net of											
issuance costs of \$0.3 million	3,026,449	39,768	—	—	—	—	—	—	—	—	—
Vesting of restricted stock	—	—	58,259	1	—	—	(1)	—	—	—	—
Conversion of convertible preferred stock into common stock and non-voting common stock	(17,219,066)	(162,553)	10,787,861	108	6,431,205	64	162,381	—	—	—	162,553
Issuance of common stock upon initial public offering, net of											
issuance costs of \$4.3 million	—	—	12,578,125	125	—	—	182,717	—	—	—	182,842
Unrealized gain on investments	—	—	—	—	—	—	—	—	29	—	29
Stock-based compensation expense	—	—	—	—	—	—	334	—	—	—	334
Net loss	—	—	—	—	—	—	—	—	—	(10,172)	(10,172)
Balance—September 30, 2019	—	\$ —	24,046,435	\$ 240	6,431,205	\$ 64	\$ 346,679	\$ —	\$ 29	\$ (92,390)	\$ 254,622

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

IGM Biosciences, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In-Capital	Due To (From) Related Party	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Share	Amount	Share	Amount				
Balance—December 31, 2017	6,384,797	\$ 40,783	438,074	\$ 4	\$ 35,479	\$ (34,625)	\$ (41,361)	\$ (40,503)
Related party equity transaction	—	—	—	—	415	(387)	—	28
Stock-based compensation expense	—	—	—	—	22	—	—	22
Net loss	—	—	—	—	—	—	(2,926)	(2,926)
Balance—March 31, 2018	6,384,797	40,783	438,074	4	35,916	(35,012)	(44,287)	(43,379)
Related party equity transaction	—	—	—	—	420	3,428	—	3,848
Stock-based compensation expense	—	—	—	—	22	—	—	22
Net loss	—	—	—	—	—	—	(4,215)	(4,215)
Balance—June 30, 2018	6,384,797	40,783	438,074	4	36,358	(31,584)	(48,502)	(43,724)
Related party equity transaction	—	—	—	—	(34,395)	42,615	—	8,220
Stock-based compensation expense	—	—	—	—	20	—	—	20
Net loss	—	—	—	—	—	—	(6,517)	(6,517)
Balance—September 30, 2018	6,384,797	\$ 40,783	438,074	\$ 4	\$ 1,983	\$ 11,031	\$ (55,019)	\$ (42,001)

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

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

	Nine Months Ended	
	September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (28,318)	\$ (13,658)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	416	191
Stock-based compensation expense	614	64
Net amortization of premiums and accretion of discounts on investments	(52)	—
Amortization of operating lease right-of-use assets	1,203	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(5,335)	(448)
Other assets	—	8
Income tax receivable	—	(35)
Accounts payable	655	(192)
Accrued liabilities	(1,377)	455
Income tax payable	—	(128)
Deferred rent	—	(108)
Lease liabilities	(819)	—
Other current liabilities	(36)	9
Other long-term liabilities	—	(9)
Net cash used in operating activities	(33,049)	(13,851)
Cash flows from investing activities:		
Purchase of property and equipment	(1,737)	(431)
Purchases of investments	(57,774)	—
Net cash used in investing activities	(59,511)	(431)
Cash flows from financing activities:		
Proceeds from new investors for issuance of Series C convertible preferred stock	72,000	—
Proceeds from related party for issuance of Series C convertible preferred stock	10,000	—
Payment of issuance costs for Series C convertible preferred stock	(220)	—
Proceeds from related party capital contribution	2,549	12,096
Proceeds from loan from related party	15,000	5,000
Proceeds from common stock issuance	11	—
Proceeds from exercise of stock options	169	—
Proceeds from issuance of initial public offering, net of underwriters' commission	187,163	—
Payment of issuance costs for initial public offering	(2,420)	—
Net cash provided by financing activities	284,252	17,096
Net increase in cash, cash equivalents and restricted cash	191,692	2,814
Cash, cash equivalents, and restricted cash, beginning of period	1,987	482
Cash, cash equivalents, and restricted cash, end of period	\$ 193,679	\$ 3,296
Cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	193,679	3,196
Restricted cash	—	100
Cash, cash equivalents, and restricted cash, end of period	\$ 193,679	\$ 3,296
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ —	\$ 167
Cash paid for interest on related party loan	\$ 297	\$ —
Supplemental disclosure of non-cash activities:		
Acquisition of property and equipment in accounts payable and accrued liabilities	\$ 84	\$ —
Issuance costs for Series C convertible preferred stock in accounts payable and accrued liabilities	\$ 144	\$ —
Settlement of related party loan through issuance of Series C convertible preferred stock	\$ 20,000	\$ —
Related party equity transaction	\$ —	\$ 34,625
Issuance costs for initial public offering in accounts payable and accrued liabilities	\$ 1,900	\$ —
Conversion of convertible preferred stock into common stock and non-voting common stock	\$ 162,553	\$ —

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

IGM Biosciences, Inc.
Notes to Unaudited Condensed Financial Statements

Note 1. Organization

Description of the Business

IGM Biosciences, Inc. (the Company) was incorporated in the state of Delaware in August 1993 under the name Palingen, Inc. and the name was subsequently changed to IGM Biosciences, Inc. in 2010. The Company's headquarters are in Mountain View, California. IGM Biosciences, Inc. is a biotechnology company engaged in the development of IgM antibody therapeutics for the treatment of cancer.

In December 2017, the Company established a holding company (Holdco); in April 2019, Holdco was subsequently dissolved and equity interests in Holdco were converted into equity interests in the Company. The information included in these financial statements is consistently presented as if it is that of the Company, even during the interim period when investors held their equity interests in Holdco. For the period ended December 31, 2018, Haldor Topsøe Holding A/S was the majority investor in the Company either through its direct equity ownership or indirectly as the majority owner of Holdco. Haldor Topsøe Holding A/S and Holdco represent a combined entity (Majority Investor) as referenced herein.

Reverse Stock Split

In August 2019, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock, non-voting common stock and convertible preferred stock, each on a 6.6084-for-1 basis (Reverse Stock Split). The Reverse Stock Split also applied to any outstanding securities or rights convertible into, or exchangeable or exercisable for, common stock, non-voting common stock or convertible preferred stock. The par value of the common stock was not adjusted as a result of the Reverse Stock Split. All references to common stock, non-voting common stock, restricted stock, options to purchase common stock, share data, per share data, convertible preferred stock and related information contained in the condensed financial statements and related footnotes have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on August 30, 2019.

Initial Public Offering

On September 17, 2019, the Company's registration statement on Form S-1 (File No. 333-233365) relating to its initial public offering (IPO) of common stock became effective. The IPO closed on September 20, 2019 at which time the Company issued an aggregate of 12,578,125 shares of its common stock at a price of \$16.00 per share, including 1,640,625 shares issued in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock. In addition, immediately prior to the closing of the IPO, all outstanding shares of the Company's convertible preferred stock automatically converted into 10,787,861 shares of common stock and 6,431,205 shares of non-voting common stock. Proceeds from the IPO, net of underwriting discounts and commissions and offering costs were approximately \$183.0 million.

Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception and had an accumulated deficit of \$92.4 million at September 30, 2019. As of September 30, 2019, the Company had cash, cash equivalents and investments of \$251.3 million. The Company has historically financed its operations primarily through the sale of convertible preferred stock and common stock and the issuance of unsecured promissory notes. To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any revenue 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 below. 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.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2018 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. These unaudited interim condensed financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair statement of the Company's financial information. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other interim period or for any other future year.

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, 2018, which are included in the Company's prospectus related to the Company's IPO, filed with the SEC on September 18, 2019, pursuant to Rule 424(b) under the Securities Act of 1933.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates, including, but not limited to, those related to investments, manufacturing accruals, accrued research and development expenses, fair value of common stock, stock-based compensation, operating lease right-of-use (ROU) assets and liabilities, income tax uncertainties and the valuation of deferred tax assets. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents and investments. The Company invests in money market funds, U.S. Treasury securities, corporate debt and commercial paper. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents and issuers of investments to the extent recorded on the condensed balance sheets. The Company's investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. Government and its agencies, corporate debt, commercial paper, and places restrictions on the credit ratings, maturities and concentration by type and issuer. The Company has not experienced any losses on its deposits of cash, cash equivalents and investments.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, the Company's early stages of clinical drug development; uncertainties related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; the Company's ability to advance product candidates into, and successfully complete, clinical trials on the timelines it projects; the Company's ability to adequately demonstrate sufficient safety and efficacy of its product candidates; the Company's ability to enroll patients in its ongoing and future clinical trials; the Company's ability to successfully manufacture and supply its product candidates for clinical trials; the Company's ability to obtain additional capital to finance its operations; uncertainties related to the projections of the size of patient populations suffering from the diseases the Company is targeting; the Company's ability to obtain, maintain, and protect its intellectual property rights; developments relating to the Company's competitors and its industry, including competing product candidates and therapies; general economic and market conditions; and other risks and uncertainties, including those more fully described in the "Risk Factors" section of this Quarterly Report on Form 10-Q.

The Company's product candidates will require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash and cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and are stated at fair value. Restricted cash consisted of a money market account that served as collateral for a credit card agreement at one of the Company's financial institutions.

Investments

The Company's investments have been classified and accounted for as available-for-sale securities. Fixed income securities consist of U.S. Treasury securities, corporate debt, and commercial paper. The specific identification method is used to determine the cost basis of fixed income securities sold. These securities are recorded on the condensed balance sheets at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive income. The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income, net. Realized gains and losses and declines in fair value judged to be other-than-temporary, if any, are also included in other income, net. The Company evaluates securities for other-than-temporary impairment at the balance sheet date. Declines in fair value determined to be other-than-temporary are also included in other income, net. The Company classifies its investments as short or long term primarily based on the remaining contractual maturity of the securities.

Research and Development Expenses

The Company expenses research and development costs as they are incurred. Research and development expenses consist primarily of: (i) personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in the Company's research and development functions; (ii) fees paid to third parties such as contractors, consultants and contract research organizations (CROs), for animal studies and other costs related to preclinical and clinical testing; (iii) costs related to acquiring and manufacturing research and clinical trial materials, including under agreements with third parties such as contract manufacturing organizations (CMOs), and other vendors; (iv) costs related to the preparation of regulatory submissions; (v) expenses related to laboratory supplies and services; and (vi) depreciation of equipment and facilities expenses.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical studies, clinical trials, and manufacturing, which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, CROs and CMOs. The Company's contracts with the CMOs generally include fees such as initiation fees, reservation fees, costs related to animal studies and safety tests, verification run costs, materials and reagents expenses, taxes, etc. The Company's contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. In the event the Company makes advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed.

The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial condition and results of operations. Through September 30, 2019, there have been no material differences from the Company's estimated accrued research and development expenses to actual expenses.

Stock-based Compensation

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all share-based awards made to employees and directors based on estimated grant-date fair values. The Company uses the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period, and estimates the fair value of share-based awards to employees and directors using the Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur. The fair value of each purchase under the employee stock purchase plan (ESPP) is estimated at the beginning of the offering period using the Black-Scholes option pricing model.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock (including non-voting common stock) outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, and filing fees directly relating to the IPO, were capitalized and offset against the IPO proceeds upon the completion of the offering. For the year ended December 31, 2018, there were no offering costs incurred. Upon completion of the IPO, approximately \$4.3 million of deferred offering costs were offset against the IPO proceeds in additional paid-in capital.

Leases

During the three months ended September 30, 2019, the Company elected to early adopt Accounting Standard Update (ASU) No. 2016-02, *Leases (Topic 842)* and its associated amendments (ASC 842) as of January 1, 2019 using the modified retrospective transition approach. There was no cumulative-effect adjustment recorded to accumulated deficit upon adoption.

Under ASC 842, the Company determines if an arrangement is a lease at inception. In addition, the Company determines whether leases meet the classification criteria of a finance or operating lease at the lease commencement date considering: (1) whether the lease transfers ownership of the underlying asset to the lessee at the end of the lease term, (2) whether the lease contains a bargain purchase option, (3) whether the lease term is for a major part of the remaining economic life of the underlying asset, (4) whether the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset, and (5) whether the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of September 30, 2019, the Company's lease population consisted of real estate. As of the date of adoption of ASC 842 and September 30, 2019, the Company did not have finance leases.

Operating leases are included in operating lease right-of-use assets, current operating lease liabilities, and non-current operating lease liabilities in the Company's condensed balance sheet. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date if the rate implicit in the lease is not readily determinable. The determination of the Company's incremental borrowing rate requires management judgment including the development of a synthetic credit rating and cost of debt as the Company currently does not carry any debt. The operating lease ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. Operating lease cost is recognized on a straight-line basis over the expected lease term. Lease agreements entered into after the adoption of ASC 842 that include lease and non-lease components are accounted for as a single lease component. Lease agreements with a noncancelable term of less than 12 months are not recorded on the Company's condensed balance sheet. For more information about the impact of adoption and disclosures on the Company's leases, refer to "Note 9 – Commitments and Contingencies."

Recently Adopted Accounting Standards

During the three months ended September 30, 2019, the Company elected to early adopt ASC 842 and its associated amendments as of January 1, 2019 using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. There was no cumulative-effect adjustment recorded to accumulated deficit upon adoption. Under the standard, a lessee is required to recognize a lease liability and ROU asset for all leases. The new guidance also modified the classification criteria and requires additional disclosures to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. Consistent with current guidance, a lessee's

recognition, measurement, and presentation of expenses and cash flows arising from a lease continue to depend primarily on its classification. The Company elected the package of three practical expedients permitted under the transition guidance, which allowed the Company to carryforward its historical lease classification, its assessment on whether a contract was or contains a lease, and its initial direct costs for any leases that existed prior to January 1, 2019. In addition, the Company elected the following transitional practical expedients: (1) the short-term lease exception and (2) to not separate its non-lease components for its real estate leases. The impact of adoption and additional disclosures required by the ASU have been included in “Significant Accounting Policies - Leases” above and in “Note 9 – Commitments and Contingencies.”

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13 *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. ASU 2016-13 also eliminates the concept of “other-than-temporary” impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact of this standard on its financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. This ASU simplifies the accounting for share-based awards to nonemployees by aligning it with the accounting for share-based awards to employees, with certain exceptions. This ASU is effective for annual periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted. The Company is currently assessing the impact of this standard on its financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which amends ASC 820, Fair Value Measurement. This ASU modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The effective date is the first quarter of fiscal year 2020, with early adoption permitted for the removed disclosures and delayed adoption until fiscal year 2020 permitted for the new disclosures. The removed and modified disclosures will be adopted on a retrospective basis and the new disclosures will be adopted on a prospective basis. The Company is currently assessing the impact of this standard on its financial statements and related disclosure.

Note 3. Fair Value Measurement

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.

Financial instruments classified within Level 2 of the fair value hierarchy are valued based on other observable inputs, including broker or dealer quotations or alternative pricing sources. When quoted prices in active markets for identical assets or liabilities are not available, the Company relies on non-binding quotes from its investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, or historical pricing trends of a security relative to its peers. To validate the fair value determination provided by its investment managers, the Company reviews the pricing movement in the context of overall market trends and trading information from its investment managers. In addition, the Company assesses the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy.

As of September 30, 2019, investments measured and recognized at fair value are as follows (in thousands)

	Fair Value Hierarchy Level	September 30, 2019			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments					
U.S. Treasury securities	Level 1	\$ 29,191	\$ 28	\$ —	\$ 29,219
Corporate bond	Level 2	8,634	1	—	8,635
Commercial paper	Level 2	19,816	—	—	19,816
Total		\$ 57,641	\$ 29	\$ —	\$ 57,670

As of December 31, 2018, there were no investments measured and recognized at fair value.

The following table presents the contractual maturities of the Company's investments as of September 30, 2019 (in thousands):

	September 30, 2019
Due in less than one year	\$ 48,396
Due in more than one year	9,274
Total	\$ 57,670

Note 4. Balance Sheet Components

Property and Equipment, Net

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

	September 30, 2019	December 31, 2018
Laboratory equipment	\$ 3,127	\$ 1,987
Office equipment	150	127
Leasehold improvement	71	25
Construction in progress	320	—
Total property and equipment, gross	3,668	2,139
Less: Accumulated depreciation	(1,083)	(667)
Total property and equipment, net	\$ 2,585	\$ 1,472

Depreciation expense was approximately \$0.2 million and \$0.1 million for the three months ended September 30, 2019 and 2018, respectively. Depreciation expense was approximately \$0.4 million and \$0.2 million for the nine months ended September 30, 2019 and 2018, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued research and development materials and services	\$ 376	\$ 2,395
Accrued professional services	226	563
Accrued compensation	1,319	177
Other	161	447
Total accrued liabilities	\$ 2,082	\$ 3,582

Note 5. Common Stock and Non-Voting Common Stock

As of September 30, 2019 and December 31, 2018, the Company's certificate of incorporation authorized the Company to issue 1,006,431,208 shares of common stock (including 6,431,208 shares of non-voting common stock) and 200,000,000 shares of preferred stock, respectively, at a par value of \$0.01 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 Company's Board of Directors, subject to prior rights of the preferred stockholders. As of September 30, 2019 and December 31, 2018, no dividends have been declared to date.

The Company had reserved common stock, on an as-converted basis, for future issuance as follows:

	September 30, 2019	December 31, 2018
Preferred stock, issued and outstanding	—	9,501,620
Restricted stock, issued and outstanding	58,259	116,518
Stock options, issued and outstanding	2,264,937	1,523,285
Stock options, future issuance	2,703,702	456,818
Employee stock purchase plan, available for future grants	280,000	—
Total	<u>5,306,898</u>	<u>11,598,241</u>

Note 6. Convertible Preferred Stock

Issued and outstanding convertible preferred stock and its principal terms as of December 31, 2018 were as follows (in thousands, except share and per share amounts):

	Authorized Shares	Shares Issued and Outstanding	Original Issue Price	Carrying Value	Aggregate Liquidation Preference
Series A convertible preferred stock	401,004	401,004	\$ 3.3042	\$ 1,325	\$ 1,325
Series B convertible preferred stock	9,100,620	9,100,616	\$ 6.6084	59,592	60,141
Total	<u>9,501,624</u>	<u>9,501,620</u>		<u>\$ 60,917</u>	<u>\$ 61,466</u>

During the nine months ended September 30, 2019, the Company issued 7,717,446 shares of Series C convertible preferred stock for total proceeds of \$102.0 million. A portion of the shares of Series C convertible preferred stock was issued to satisfy the settlement of an unsecured promissory note amounting to \$20.0 million.

Immediately prior to the closing of the IPO, all outstanding shares of the Company's convertible preferred stock converted into 10,787,861 shares of common stock and 6,431,205 shares of non-voting common stock and the related carrying value was reclassified to common stock, non-voting common stock and additional paid-in capital. There were no shares of convertible preferred stock outstanding as of September 30, 2019.

Note 7. Stock-Based Compensation

2018 Omnibus Incentive Plan (as Amended and Restated)

The Company's Board of Directors adopted and the Company's stockholders approved, effective on the day prior to the effectiveness of the registration statement on Form S-1 related to the IPO, an amendment and restatement of the 2018 Omnibus Incentive Plan (the 2018 Plan) which provides for the grant of incentive stock options, within the meaning of Section 422 of the Code to employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units (RSUs), stock appreciation rights, performance units, and performance shares to employees, directors, and consultants of the Company.

Options granted under the 2018 Plan expire no later than 10 years from the date of grant. The exercise price of options granted under the 2018 Plan must at least be equal to the fair market value of the Company's common stock on the date of grant. With respect to any participant who owns more than 10% of the voting power of all classes of the Company's outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. Employee stock options generally vest 25% upon one year of continued service to the Company, with the remainder in monthly increments over three additional years.

Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 4,384,000 shares of the Company's common stock for issuance pursuant to awards under the 2018 Plan. The 2018 Plan is administered by the Compensation Committee of the Company's Board of Directors. The number of shares of the Company's common stock available for issuance under the 2018 Plan will also include an annual increase on the first day of each fiscal year beginning with the 2020 fiscal year, equal to the least of (i) 8,768,800 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Company's Board of Directors. As of September 30, 2019, 2,703,702 shares of common stock remained available for issuance under the 2018 Plan.

2010 Stock Plan (as Amended and Restated)

The 2010 Stock Plan (the 2010 Plan) was originally adopted by the Company's Board of Directors and approved by the Company's stockholders in November 2010. The 2010 Plan was amended in December 2017. The 2010 Plan allowed the Company to provide incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options and stock purchase rights to eligible employees, consultants and directors and any parent or subsidiary of the Company. The 2010 Plan was terminated in 2019 and the Company will not grant any additional awards under the 2010 Plan. However, the 2010 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2010 Plan.

2019 Employee Stock Purchase Plan

The Company's Board of Directors adopted and the Company's stockholders approved, effective on the day prior to the effectiveness of the registration statement on Form S-1 related to the IPO, the 2019 Employee Stock Purchase Plan (ESPP). However, no offering period or purchase period under the ESPP will begin unless and until determined by the Company's Board of Directors. The ESPP is intended to have two components: a component that is intended to qualify as an "employee stock purchase plan" under Section 423 of the Code (the 423 Component) and a component that is not intended to qualify (the Non-423 Component). The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation. At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock at the beginning of the offering period or at the end of each applicable purchase period.

Subject to adjustment in the case of certain capitalization events, a total of 280,000 common shares of the Company were available for purchase at adoption of the ESPP. Pursuant to the ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 560,000 shares, (ii) 1% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Company's Board of Directors. As of September 30, 2019, 280,000 shares of common stock remained available for issuance under the ESPP.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded related to the 2010 Plan, 2018 Plan, and ESPP was recorded in the condensed statements of operations and allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 116	\$ 9	\$ 330	\$ 26
General and administrative	218	12	284	38
Total stock-based compensation expense	\$ 334	\$ 21	\$ 614	\$ 64

Stock Options

The following table summarizes stock option activity.

	Shares Available for Grant	Outstanding Options		Weighted-Average Remaining Contractual Term (Years)
		Shares	Weighted-Average Exercise	
Balance—December 31, 2018	456,818	1,523,285		
Addition - Option pool	3,165,087	—		
Granted	(929,561)	929,561	\$ 5.63	
Exercised	—	(176,551)	0.96	
Cancelled	11,358	(11,358)	1.08	
Balance—September 30, 2019	<u>2,703,702</u>	<u>2,264,937</u>	\$ 3.01	8.3
Exercisable – September 30, 2019		<u>841,852</u>	1.31	6.4

There were no options granted during the three and nine months ended September 30, 2018. The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected term in years	6.0	—	6.0	—
Expected volatility	79.4%	—	79.3%	—
Risk-free interest rate	1.6%	—	2.2%	—
Dividend yield	—	—	—	—
Weighted average fair value of share-based awards granted	\$ 8.8	—	\$ 3.9	—

The fair value of ESPP was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected term in years	0.7	—	0.7	—
Expected volatility	74.3%	—	74.3%	—
Risk-free interest rate	1.9%	—	1.9%	—
Dividend yield	—	—	—	—

Restricted Stock

During December 2018, the Company issued 116,518 shares of common stock to an executive officer under a restricted stock agreement at a grant date fair value of \$1.39 per share that vests over two years. Any unvested shares are subject to forfeiture in the case that the grantee's service terminates. As of September 30, 2019, 58,259 shares of restricted stock were vested. For the three and nine months ended September 30, 2019, the related stock-based compensation was immaterial. As of September 30, 2019, there was \$0.1 million of unrecognized stock-based compensation related to restricted stock, which the Company expects to recognize over a remaining weighted-average period of 0.8 years.

Note 8. Net Loss Per Share Attributable to Common Stockholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	\$ (10,172)	\$ (6,517)	\$ (28,318)	\$ (13,658)
Denominator:				
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	4,222,259	438,074	1,755,526	438,074
Net loss per share attributable to common stockholders	\$ (2.41)	\$ (14.88)	\$ (16.13)	\$ (31.18)

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

	September 30,	
	2019	2018
Series A convertible preferred stock	—	401,004
Series B convertible preferred stock	—	5,983,793
Restricted stock	58,259	—
Stock options	2,264,937	768,762
Total	2,323,196	7,153,559

Note 9. Commitments and Contingencies

Operating Leases

The Company leases its headquarters with its main offices and laboratory facilities in Mountain View, California under a lease agreement that ends in April 2025.

During the three months ended September 30, 2019, the Company early adopted ASC 842 and its associated amendments as of January 1, 2019 using the modified retrospective transition approach by applying the new standard to all leases existing at the date of the initial application and not restating comparative periods. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carryforward the historical lease classification of those leases in place as of January 1, 2019. The adoption of ASC 842 resulted in an increase to total assets and liabilities due to the recording of operating lease ROU assets and operating lease liabilities of approximately \$0.6 million and \$0.7 million, respectively, as of January 1, 2019. ROU assets and lease liabilities are recognized based on the present value of the fixed and in-substance fixed lease payments over the lease term at the commencement date. The ROU assets also include any initial direct costs incurred and lease payments made at or before the commencement date and are reduced by lease incentives. Variable lease costs represent payments that are dependent on usage, a rate or index. Variable lease cost primarily relates to common area maintenance charges for its real estate leases as the Company elected not to separate non-lease components from lease components upon adoption of ASC 842. Because the rate implicit in each lease is not readily determinable, the Company uses its incremental borrowing rate to determine the present value of the lease payments. As noted in "Note 10 -Related Party Transactions with its Majority Investor," the Company entered into an agreement with the Majority Investor in February 2019 whereby the Majority Investor lent its credit and worthiness to the Company. The Company determined the incremental borrowing rates for its leases by adjusting the observable risk-free interest rate with a credit risk premium corresponding to the Majority Investor's credit rating.

Information related to the Company's ROU assets and related lease liabilities were as follows (in thousands except for remaining lease term and discount rate):

	September 30, 2019
Cash paid for operating lease liabilities	\$ 983
Right-of-use assets recognized in exchange for new lease obligations	9,882
Current operating lease liabilities	1,564
Non-current operating lease liabilities	8,810
Weighted average remaining lease term	5.6
Weighted average discount rate	3.5%

Maturities of lease liabilities as of September 30, 2019 were as follows (in thousands):

Year Ending December	Operating Lease Commitments
2019 (remaining three months)	\$ 455
2020	1,935
2021	1,993
2022	2,053
2023	2,115
2024	2,178
Thereafter	734
Total	11,463
Less imputed interest	(1,089)
Total lease liabilities	<u>\$ 10,374</u>

Rent expense for three and nine months ended September 30, 2019 was \$0.7 million and \$1.4 million, respectively, which includes additional rent charges for common area maintenance.

Rent expense for the three and nine months ended September 30, 2018 was \$0.2 million and \$0.5 million, respectively. Future minimum lease payments as of December 31, 2018 are \$0.7 million in 2019.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the nine months ended September 30, 2019 and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. 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, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual 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.

Note 10. Related Party Transactions with its Majority Investor

The following are transactions that occurred between the Company and the Majority Investor, as defined in Note 1.

Lease Guarantee

In February 2019, the Majority Investor entered into an agreement to lend its credit and creditworthiness to the Company by providing a guarantee to allow the Company to enter into the lease agreement for its facilities in Mountain View, California. The Company has not drawn on the guarantee nor incurred any related commission expense through September 30, 2019.

Settlement of Related Party Receivable

In April 2019, the Company received \$2.5 million in cash from the Majority Investor in settlement of the outstanding note receivable as of December 31, 2018.

Related Party Loan

In January, February and April 2019, the Company issued an unsecured promissory note to the Majority Investor for proceeds of \$15.0 million. In June 2019, the outstanding unsecured promissory note, amounting to \$20.0 million, issued by the Majority Investor was settled as shares of Series C convertible preferred stock (see below). During the three and nine months ended September 30, 2019, the Company paid \$0.3 million in interest related to the unsecured promissory note issued to the Majority Investor.

2019 Series C Issuance

In June 2019, the Company issued 2,269,838 shares of Series C convertible preferred stock to the Majority Investor for \$30.0 million. A portion of the shares of Series C convertible preferred stock was issued to satisfy the settlement of the unsecured promissory note amounting to \$20.0 million issued by the Majority Investor.

Initial Public Offering

Immediately prior to the closing of the IPO, all outstanding shares of the Company's convertible preferred stock held by the Majority Investor automatically converted into common stock and non-voting common stock. The Majority Investor also purchased an additional 1,250,000 shares of common stock in connection with the IPO. As a result of these two events, the Majority Investor owned 10,289,453 shares of common stock and 2,269,838 shares of non-voting common stock, upon closing of the IPO.

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.

Overview

We are a biotechnology company pioneering the development of engineered IgM antibodies for the treatment of cancer patients. IgM antibodies have inherent properties that we believe may enable them to bind more strongly to cancer cells than comparable IgG antibodies. We have created a proprietary IgM antibody technology platform that we believe is particularly well suited for developing T cell engagers, receptor cross-linking agonists and targeted cytokines. Our lead product candidate, IGM-2323, is a bispecific T cell engaging IgM antibody targeting CD20 and CD3 proteins, and in October 2019 we announced the dosing of the first patient in our Phase 1 clinical trial for the treatment of relapsed/refractory B cell Non-Hodgkin's lymphoma (NHL) patients. Our second product candidate will be an IgM antibody targeting Death Receptor 5 (DR5) proteins, and we plan to file an investigational new drug application (IND) for the treatment of patients with solid and hematologic malignancies in 2020. We believe that we have the most advanced research and development program focused on engineered therapeutic IgM antibodies. We have created a portfolio of patents and patent applications, know-how and trade secrets directed to our platform technology, product candidates and manufacturing capabilities, and we retain worldwide commercial rights to all of our product candidates and the intellectual property related thereto.

Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, developing our in-house manufacturing capabilities, hiring personnel, raising capital and providing general and administrative support for these operations. Since 2010, such activities have exclusively related to the research, development and manufacture of IgM antibodies and to building our proprietary IgM antibody technology platform. We do not have any products approved for sale, and we have not generated any revenue from product sales.

We have incurred significant net losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were \$28.3 million and \$13.7 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of \$92.4 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. In addition, we expect to incur additional costs associated with operating as a public company.

We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance the development of IGM-2323;
- advance the development of our DR5 IgM antibody;
- expand our pipeline of IgM antibody product candidates;
- continue to invest in our IgM antibody technology platform;
- build out and expand our in-house manufacturing capabilities;
- maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know-how;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out;
- implement operational, financial and management information systems; and
- attract, hire and retain additional clinical, scientific, management and administrative personnel.

We plan to continue to use third-party service providers, including clinical research organizations (CROs) and clinical manufacturing organizations (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.

We do not have any products approved for sale and have not generated any revenue since inception. Prior to the completion of our initial public offering (IPO) in September 2019, we had funded our operations primarily with an aggregate of approximately \$162.0 million in gross cash proceeds from the sale of convertible preferred stock and issuance of unsecured promissory notes.

In September 2019, we completed our IPO and sold and issued an aggregate of 12,578,125 shares of common stock, including 1,640,625 shares issued in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock, at \$16.00 per share for gross proceeds of \$201.3 million. The aggregated net proceeds from our IPO, inclusive of the full exercise by the underwriters of their option to purchase additional shares of common stock, were approximately \$183.0 million after deducting underwriting discounts and commissions and other offering costs. Immediately prior to the closing of our IPO, all shares of convertible preferred stock then outstanding automatically converted into 10,787,861 shares of common stock and 6,431,205 shares of non-voting common stock.

We were incorporated in Delaware in 1993 under the name Palingen, Inc. From 1993 to 2010, we were principally engaged in research related to naturally occurring IgM antibodies. In 2010, we received an initial equity investment from Haldor Topsøe Holding A/S, changed our name to IGM Biosciences, Inc. and refocused our research and development efforts toward developing our IgM platform and engineering new IgM antibodies. In December 2017, we established a Danish holding company—IGM Biosciences A/S (Holdco); in April 2019, we dissolved Holdco. The capitalization information included in this Quarterly Report on Form 10-Q is consistently presented as that of IGM Biosciences, Inc. even during the interim period when we had a holding company structure and our investors held their equity interests in Holdco.

Components of Results of Operations

Revenue

To date, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for the discovery and development of product candidates, which include:

Direct expenses consisting of:

- Fees paid to third parties such as consultants, contractors and CROs, for animal studies and other costs related to preclinical studies and clinical trials;
- Costs related to acquiring and manufacturing research and clinical trial materials, including under agreements with third parties such as CMOs and other vendors;
- Costs related to the preparation of regulatory submissions; and
- Expenses related to laboratory supplies and services;

Indirect expenses consisting of:

- Personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in our research and development functions; and
- Depreciation of equipment and facilities expenses.

We expense research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. All direct research and development expenses are tracked by stage of development. We do not track our indirect research and development costs by product candidate or program.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities to advance our product candidates and our clinical programs, expand our product candidate pipeline and continue to build out and expand our in-house manufacturing capabilities. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. To the extent that our product candidates continue to advance into clinical trials, as well as advance into larger and later stage clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products. As a result of these variables, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses for personnel in our executive, finance, corporate and other administrative functions, intellectual property, facilities and other allocated expenses, other expenses for outside professional services, including legal, human resources, audit and accounting services, and insurance costs. Personnel-related expenses consist of salaries, benefits and stock-based compensation. We expect our general and administrative expenses to increase for the foreseeable future as we increase our headcount to support our continued research activities and development of product candidates and as a result of operating as a public company, including compliance with the rules and regulations of the Securities and Exchange Commission (SEC) and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

Other Income, Net

Other income, net includes sublease income, interest income earned on our cash, cash equivalents, investments, and restricted cash balances and interest expense incurred on unsecured promissory notes.

Results of Operations

Comparison of Three Months Ended September 30, 2019 and 2018

Our condensed statements of operations as discussed herein are presented below:

<i>(in thousands)</i>	Three Months Ended		Change
	September 30,		
	2019	2018	
<i>Operating expenses:</i>			
Research and development	\$ 8,279	\$ 5,172	\$ 3,107
General and administrative	2,394	1,373	1,021
Total operating expenses	<u>10,673</u>	<u>6,545</u>	<u>4,128</u>
Loss from operations	(10,673)	(6,545)	(4,128)
Other income, net	501	28	473
Net loss	<u>\$ (10,172)</u>	<u>\$ (6,517)</u>	<u>\$ (3,655)</u>

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated:

<i>(in thousands)</i>	Three Months Ended September 30,		Change
	2019	2018	
Direct expenses			
Clinical stage program ⁽¹⁾	\$ 1,999	\$ 1,793	\$ 206
Preclinical stage programs	2,324	1,734	590
Indirect expenses			
Personnel-related	2,708	1,287	1,421
Depreciation and facilities	1,248	358	890
Total research and development expenses	<u>\$ 8,279</u>	<u>\$ 5,172</u>	<u>\$ 3,107</u>

(1) Includes direct expenses related to our lead product candidate, IGM-2323, for which we announced the dosing of the first patient in our Phase 1 clinical trial in October 2019.

Research and development expenses were \$8.3 million for the three months ended September 30, 2019, compared to \$5.2 million for the three months ended September 30, 2018. The increase of \$3.1 million was primarily driven by an increase of \$1.4 million in personnel-related expenses, including stock-based compensation, due to an increase in headcount. Clinical and preclinical stage programs increased by \$0.8 million which consisted of expenses for our IGM-2323 Phase 1 clinical trial for which we announced the dosing of the first patient in October 2019. Depreciation and facilities increased by \$0.9 million primarily due to a new lease agreement for additional office, laboratory and manufacturing space in Mountain View which commenced in May 2019.

General and Administrative Expenses

General and administrative expenses were \$2.4 million for the three months ended September 30, 2019 compared to \$1.4 million for the three months ended September 30, 2018. The increase of \$1.0 million was primarily due to a \$0.7 million increase in personnel-related expenses, including stock-based compensation, due to an increase in headcount, and a \$0.1 million increase in facilities-related expenses due to a new lease agreement for additional office, laboratory and manufacturing space in Mountain View which commenced in May 2019.

Other Income, Net

Other income, net was \$0.5 million for the three months ended September 30, 2019 compared to \$28,000 for the three months ended September 30, 2018. The increase of \$0.5 million was primarily due to interest earned from higher cash equivalent and investment balances.

Comparison of Nine Months Ended September 30, 2019 and 2018

Our condensed statements of operations as discussed herein are presented below:

<i>(in thousands)</i>	Nine Months Ended September 30,		Change
	2019	2018	
Operating expenses:			
Research and development	\$ 22,494	\$ 11,148	\$ 11,346
General and administrative	6,067	2,597	3,470
Total operating expenses	<u>28,561</u>	<u>13,745</u>	<u>14,816</u>
Loss from operations	<u>(28,561)</u>	<u>(13,745)</u>	<u>(14,816)</u>
Other income, net	243	87	156
Net loss	<u>\$ (28,318)</u>	<u>\$ (13,658)</u>	<u>\$ (14,660)</u>

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated:

<i>(in thousands)</i>	Nine Months Ended September 30,		Change
	2019	2018	
Direct expenses			
Clinical stage program ⁽¹⁾	\$ 7,329	\$ 2,927	\$ 4,402
Preclinical stage programs	6,045	3,819	2,226
Indirect expenses			
Personnel-related	6,640	3,383	3,257
Depreciation and facilities	2,480	1,019	1,461
Total research and development expenses	<u>\$ 22,494</u>	<u>\$ 11,148</u>	<u>\$ 11,346</u>

(1) Includes direct expenses related to our lead product candidate, IGM-2323, for which we announced the dosing of the first patient in our Phase 1 clinical trial in October 2019.

Research and development expenses were \$22.5 million for the nine months ended September 30, 2019, compared to \$11.1 million for the nine months ended September 30, 2018. The increase of \$11.3 million was driven by an increase in expenses to advance our product candidates, including \$4.4 million of expenses related to our clinical stage program, which consisted of preclinical and manufacturing expenses incurred in the development of our lead product candidate, IGM-2323, and expenses for its Phase 1 clinical trial for which we announced the dosing of the first patient in October 2019, and \$2.2 million related to our preclinical stage programs. Personnel-related expenses, including stock-based compensation, increased by \$3.3 million due to an increase in headcount. Depreciation and facilities increased by \$1.5 million primarily due to a new lease agreement for additional office, laboratory and manufacturing space in Mountain View which commenced in May 2019.

General and Administrative Expenses

General and administrative expenses were \$6.1 million for the nine months ended September 30, 2019 compared to \$2.6 million for the nine months ended September 30, 2018. The increase of \$3.5 million was primarily due to a \$1.5 million increase in professional services which consisted of legal, accounting and consulting services in preparation for our public company status, a \$1.4 million increase in personnel-related expenses, including stock-based compensation, and a \$0.2 million increase in facilities-related expenses due to a new lease agreement for additional office, laboratory and manufacturing space in Mountain View which commenced in May 2019.

Other Income, Net

Other income, net was \$0.2 million for the nine months ended September 30, 2019 compared to \$0.1 million for the nine months ended September 30, 2018. The increase of \$0.1 million was primarily due to interest earned from higher cash equivalent and investment balances and a decrease in interest expense from an interest-bearing unsecured promissory note.

Liquidity and Capital Resources

Liquidity

Due to our significant research and development expenditures, we have generated operating losses since our inception. We have funded our operations primarily through the sale of convertible preferred stock and common stock and the issuance of unsecured promissory notes. As of September 30, 2019, we had cash, cash equivalents and investments of \$251.3 million. As of September 30, 2019, we had an accumulated deficit of \$92.4 million. We believe that our cash, cash equivalents and investments will be sufficient to fund our planned operations into early 2022.

Future Funding Requirements

Our primary uses of cash are to fund operating expenses, which consist primarily of research and development expenditures related to our programs and related personnel costs. The timing and amount of our future funding requirements depends on many factors, including the following:

- the initiation, scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates, including building out and expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and cost of capital expenditures to support our research, development and manufacturing efforts;
- the number and characteristics of other product candidates that we pursue;
- the costs, timing and outcome of seeking and obtaining U.S. Food and Drug Administration (FDA) and non-U.S. regulatory approvals;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

In addition, we will continue to require additional funding in order to complete development of our product candidates and commercialize our products, if approved. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. There can be no assurance that, in the event we require additional financing, such financing will be available at terms acceptable to us, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on our ability to achieve our intended business objectives. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs at an earlier stage of development or on less favorable terms than we would otherwise choose or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs.

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:

	Nine Months Ended September 30,	
<i>(in thousands)</i>	2019	2018
Net cash used in operating activities	(33,049)	(13,851)
Net cash used in investing activities	(59,511)	(431)
Net cash provided by financing activities	284,252	17,096

Cash Used in Operating Activities

For the nine months ended September 30, 2019, cash used in operating activities was \$33.0 million, which consisted of a net loss of \$28.3 million and a net change of \$6.9 million in our net operating assets and liabilities, partially offset by \$2.2 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to a decrease in accrued liabilities of \$1.4 million, a decrease in lease liabilities of \$0.8 million, and an increase in prepaid expenses of \$5.3 million, partially offset by an increase in accounts payable of \$0.7 million. The non-cash charges primarily consisted of stock-based compensation of \$0.6 million, depreciation expense of \$0.4 million, and amortization of operating lease right-of-use assets of \$1.2 million.

For the nine months ended September 30, 2018, cash used in operating activities was \$13.9 million, which consisted of a net loss of \$13.7 million and a net change of \$0.4 million in our net operating assets and liabilities, partially offset by \$0.3 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to an increase in prepaid expenses of \$0.4 million, a decrease in accounts payable of \$0.2 million, a decrease in deferred rent of \$0.1 million, and a decrease in income tax payable of \$0.1 million, offset by an increase in accrued liabilities of \$0.5 million. The non-cash charges primarily consisted of depreciation expense of \$0.2 million.

Cash Used in Investing Activities

For the nine months ended September 30, 2019, cash used in investing activities was \$59.5 million, which consisted of \$57.8 million in purchases of investments and \$1.7 million in purchases of lab equipment for research and development activities.

For the nine months ended September 30, 2018, cash used in investing activities consisted of \$0.4 million related to the purchases of lab equipment for research and development activities.

Cash Provided by Financing Activities

For the nine months ended September 30, 2019, cash provided by financing activities was \$284.3 million, which consisted primarily of \$184.7 million of net proceeds from our IPO, \$81.8 million of net proceeds from the issuance of shares of our Series C convertible preferred stock, \$15.0 million of proceeds from the issuance of an unsecured promissory note to a related party which was subsequently settled as Series C convertible preferred stock in June 2019, the receipt of a \$2.5 million receivable that was due from a related party, and \$0.2 million from the issuance of common stock and exercise of stock options.

For the nine months ended September 30, 2018, cash provided by financing activities was \$17.1 million, which consisted of a loan from a related party of \$5.0 million and proceeds from related party capital contribution of \$12.1 million.

Contractual Obligations and Commitments

As of September 30, 2019, there have been no material changes from the contractual obligations and commitments as of June 30, 2019 previously disclosed in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the Securities Act) with the SEC on September 18, 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 and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (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 in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 18, 2019 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the nine months ended September 30, 2019, 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 final prospectus filed on September 18, 2019.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. There was no material foreign currency risk for the nine months ended September 30, 2019. We held \$251.3 million in cash, cash equivalents and investments as of September 30, 2019. We generally hold our cash in interest-bearing money market accounts. We held no interest-bearing liabilities as of September 30, 2019. Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 4. Controls and Procedures.

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, 2019.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2019, we implemented ASC Topic 842, *Leases*, effective January 1, 2019. As a result, we implemented changes to our policies, processes, and control activities to support the adoption of ASC Topic 842. Additionally, during the quarter ended September 30, 2019, we implemented policies, processes, and controls to support the valuation and classification of our investment portfolio.

Other than the items described above, there were no changes in internal control over financial reporting during the quarter ended September 30, 2019 that materially affected internal control over financial reporting or are likely to materially affect it.

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.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm 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 the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Business and the Development and Commercialization of Our Product Candidates

We are early in our development efforts and all of our product candidates are in preclinical development or early stage clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and commercialize one or more of our product candidates, our business will be materially adversely affected and we may never generate any product revenue.

We are early in our development efforts and have not yet completed the development of any of our product candidates. As a result, we are not currently permitted to market or sell any of our product candidates in any country, and we may never be able to do so in the future. We have a limited number of product candidates and discovery programs, all of which are in preclinical development or early stage clinical development. We have begun dosing patients in our Phase 1 clinical trial evaluating IGM-2323, our lead product candidate, but have not commenced any other clinical trial or completed any clinical trials, and we have not received marketing approval, for any of our product candidates. Our product candidates will require clinical development, evaluation of preclinical, clinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we generate any revenues from product sales, if ever. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals. Our ability to generate product revenue and achieve and sustain profitability depends on, among other things, obtaining regulatory approvals for our product candidates. Obtaining regulatory approval of our product candidates will depend on many factors, including, but not limited to, the following:

- completing process development, manufacturing and formulation activities;
- initiating, enrolling patients in and completing clinical trials of product candidates on a timely basis;
- developing and maintaining adequate manufacturing capabilities either by ourselves or in connection with third-party manufacturers; and
- demonstrating with substantial evidence the efficacy, safety and tolerability of product candidates to the satisfaction of the FDA or any comparable foreign regulatory authority for marketing approval.

Many of these factors are wholly or partially beyond our control, including clinical advancement, the regulatory submission process and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to develop product candidates at all, and our business will be materially adversely affected.

The use of engineered IgM antibodies is a novel and unproven therapeutic approach and our development of IGM-2323, our DR5 IgM antibody and our discovery programs may never lead to a marketable product.

Our product candidates are based on engineered IgM antibody approaches that differ from current antibody therapies and are unproven. Our IgM antibodies ultimately may not be as safe or effective as IgG antibodies that have been approved or may in the future be approved by the FDA. Further, we are not aware of any therapeutic IgM antibodies that have been approved by the FDA. The scientific evidence to support the feasibility of developing our product candidates and discovery programs is both preliminary and limited. We may ultimately discover that our product candidates and discovery programs do not possess some of the properties that are necessary for therapeutic efficacy, and we may also discover that they do not possess those characteristics that we believe may be helpful for therapeutic effectiveness, including stronger binding that increases efficacy. Our IgM antibodies may also have significant undesirable characteristics, such as immunogenicity, which would limit their ability to be developed as effective and safe therapeutics. In addition, we may discover that our IgM antibodies are not as safe as IgG antibodies.

We may not succeed in demonstrating safety and efficacy of these product candidates or discovery programs in clinical trials, notwithstanding results in preclinical studies. As a result, we may never succeed in developing a marketable product. We may discover that the half-life, tissue distribution or other pharmacodynamic or pharmacokinetic characteristics of our IgM antibodies render them unsuitable for the therapeutic applications we have chosen or are not competitive with IgG antibodies. We may also experience manufacturing, formulation or stability problems with one or more of our IgM antibodies which may render them unsuitable for use as therapeutic drug products.

The FDA has limited experience with IgM antibody-based therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, the FDA may require us to provide additional data to support our regulatory applications. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be subject to post-marketing testing requirements to maintain regulatory approval. In addition, upon obtaining any marketing approvals, we may have difficulty in establishing the necessary sales and marketing capabilities to gain market acceptance.

Moreover, advancing IGM-2323, our DR5 IgM antibody and our discovery programs as novel products creates other significant challenges for us, including educating medical personnel regarding a novel class of engineered antibody therapeutics and their potential efficacy and safety benefits, as well as the challenges of incorporating our product candidates, if approved, into treatment regimens.

If any of our product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, and it may prove to be difficult or impossible to finance the further development of our pipeline. Any of these events would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities or provide the basis for regulatory approval.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials to demonstrate their safety and efficacy. Clinical testing is expensive and difficult to design and implement. Clinical testing can take many years to complete, and its ultimate outcome is uncertain.

A failure of one or more clinical trials can occur at any stage of the process. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Interim or preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

In October 2019, we announced the dosing of the first patient in our Phase I clinical trial evaluating IGM-2323, our lead product candidate, for the treatment of relapsed/refractory B cell NHL patients, and we expect to file an IND for our second product candidate, an IgM antibody targeting DR5, for the treatment of patients with solid and hematological malignancies in 2020. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of these clinical trials could be substantially delayed or prevented by many factors, including:

- further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or clinical research organizations (CROs), the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board (IRB) approval to conduct a clinical trial at a prospective site;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the inability to produce or obtain sufficient quantities of a product candidate to complete clinical trials;
- inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- the need to suspend, repeat or terminate clinical trials as a result of non-compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason by, any future strategic partners that have responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we experience delays or difficulties in the enrollment of patients in clinical trials, including as a result of competition for patients, we will be unable to complete these trials on a timely basis, if at all.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the severity of the disease under investigation, the proximity of subjects to clinical sites, continued enrollment of prospective patients by clinical trial sites, efforts to facilitate timely enrollment, the eligibility criteria for the trial, the design of the clinical trial, patient referral practices of physicians, ability to obtain and maintain patient consents, ability to monitor patients adequately during and after treatment, risk that enrolled subjects will drop out before completion and clinicians' and patients' perceptions as to the potential advantages and disadvantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites. Moreover, because our product candidates represent a departure from existing cancer treatments, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, IgG antibody therapy or CAR-T treatment, rather than enroll patients in our clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. If we are unable to enroll a sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for such product candidates and our business will be harmed. Even if we are able to enroll a sufficient number of patients in our clinical studies or trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public for any indication.

All of our product candidates and discovery programs are in preclinical development or early stage clinical development, and not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from our product candidates could arise at any time during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. In October 2019, we announced the dosing of the first patient in our Phase 1 clinical trial for our lead product candidate, IGM-2323, but we do not yet have any safety data in humans. Our DR5 IgM antibody and our discovery programs are still in preclinical development and have not been tested on humans at all.

In our preclinical studies, we may observe undesirable characteristics of our product candidates. This may prevent us from advancing them into clinical trials, delay these trials or limit the extent of these trials. For example, we have observed some indications of toxicity at high doses in our *in vitro* studies in human hepatocytes and *in vivo* non-human primate studies for our DR5 IgM antibody. The dose levels where this *in vitro* toxicity was observed are significantly higher than the maximum dose levels we anticipate using in our clinical trials. Nonetheless, toxicity observations in clinical testing, if they occur, may limit our ability to develop a DR5 antibody or may constitute a dose limiting toxicity.

The results of future clinical trials may also show that IGM-2323, our DR5 IgM antibody and/or our discovery programs may cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or comparable foreign regulatory authorities, or result in marketing approval from the FDA or comparable foreign regulatory authorities with restrictive label warnings or for limited patient populations, or result in potential product liability claims. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication.

Even if any of our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindication, precaution or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, limit the patient population who can use the product or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future products.

We face significant competition from entities that have developed or may develop product candidates for the treatment of diseases that we are initially targeting, including companies developing novel treatments and technology platforms. If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The development and commercialization of drugs and therapeutic biologics is highly competitive and subject to rapid and significant technological change. We are currently developing biotherapeutics that will compete with other drugs and therapies that currently exist or are being developed in the segments of the pharmaceutical, biotechnology and other related markets that develop immuno-oncology treatments. Product candidates we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do.

There are a large number of companies developing or marketing treatments for cancer, including most major pharmaceutical and biotechnology companies, as well as many smaller biotechnology companies. These treatments consist both of small molecule drug products, as well as biologics that work by using antibody therapeutic platforms to address specific cancer targets. In addition, many companies, including large pharmaceutical and biotechnology companies such as AbbVie, Amgen, AstraZeneca/MedImmune, Bristol-Myers Squibb, Merck, Novartis, Pfizer and Roche/Genentech, are also developing immuno-oncology treatments for cancer.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (e.g., T cell engagers), adoptive cellular therapies (e.g., CAR-T), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin and targeted cancer vaccines.

With respect to our lead product candidate, IGM-2323, we are aware of other companies with competing clinical stage therapeutics that target CD20 that include, but are not limited to, Roche/Genentech, Regeneron, Xencor and Genmab.

With respect to our second product candidate, our DR5 IgM antibody, we are aware of other companies with competing clinical stage therapeutics that target DR5 that include, but are not limited to, AbbVie, InhibRx, Genmab and Boehringer Ingelheim.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than the products that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

The manufacturing of our product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.

We have spent significant resources to date on developing our current manufacturing processes and know-how to produce sufficient yields and optimize functionality in conjunction with our contract manufacturers. We plan to construct our own manufacturing facility to produce our product candidates in sufficient quantities to conduct clinical trials and ultimately commercial supply for any approved products. To do so, we will need to scale our manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient yields needed to advance our product candidates and discovery programs in preclinical studies and clinical trials. Accordingly, we will be required to make significant investments to expand our manufacturing facilities in the future, and our efforts to scale our internal manufacturing capabilities may not succeed.

Also, historically IgM antibodies have been particularly difficult to manufacture and CMOs have limited experience in the manufacturing of IgM antibodies. The process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. On at least one occasion in the past, one of our contract manufacturers has failed to successfully complete a scheduled manufacturing run of our IgM antibodies as a result of their manufacturing process errors. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

All of our engineered antibodies are manufactured by culturing cells from a master cell bank. We have one master cell bank for each antibody manufactured in accordance with current good manufacturing practices (cGMPs). It is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks, and we may fail to have adequate backup should any particular cell bank be lost in a catastrophic event. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts and the use of engineered IgM antibodies is a novel therapeutic approach. Failure to develop our own manufacturing capacity may hamper our ability to further process improvement, maintain quality control, limit our reliance on contract manufacturers and protect our trade secrets and other intellectual property.

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

A key element of our strategy is to leverage our IgM platform to expand our pipeline of antibody product candidates. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers, we may not be able to develop product candidates that are safe and effective. In addition, although we expect that our IgM platform will allow us to develop a steady stream of product candidates, we may not prove to be successful at doing so. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance. If we do not successfully develop and begin to commercialize product candidates, we will not be able to generate any product revenue, which would adversely affect business.

We may expend our limited resources to pursue product candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our programs, we must focus our programs on specific product candidates and indications and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or indications may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the oncology or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the business, research and development and clinical expertise of Mr. Fred Schwarzer, our Chief Executive Officer, Dr. Bruce Keyt, our Chief Scientific Officer, Dr. Daniel Chen, our Chief Medical Officer, and Mr. Misbah Tahir, our Chief Financial Officer, as well as other members of our senior management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, manufacturing, and sales and marketing personnel, and we face significant competition for experienced personnel. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Intense competition for attracting key skill-sets may limit our ability to retain and motivate these key personnel on acceptable terms.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

The design or execution of our future clinical trials may not support regulatory approval.

The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in potential future Phase 3 clinical trials or registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. Failure to successfully obtain regulatory approval could have a material adverse impact on our business and financial performance.

Even if any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive price and otherwise will be accepted in the market. The antibodies we are developing use relatively new technologies. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our technologies, and the medical community and third-party payors may not accept and use, or provide favorable reimbursement for, any product candidates developed by us. The commercial success of our product candidates will depend upon their acceptance among physicians, patients, the medical community and third-party payors. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- limitations or warnings contained in the approved labeling for our product candidates;
- changes in the standard of care for the targeted indications for our product candidates;
- the clinical indications for which any product candidate is approved;
- lack of significant adverse side effects;
- the effectiveness of sales and marketing efforts;
- availability and extent of coverage and adequate reimbursement, as well as pricing, by managed care plans and other third-party payors, including government authorities;
- patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payors;

- timing of market introduction of our product candidate as well as competitive products;
- the potential and perceived advantages of our product candidate over alternative treatments;
- the degree of cost-effectiveness of our product candidate;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- the extent to which any product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second or third-line therapy for particular indications;
- whether our product candidate can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our product candidate or favorable publicity about competitive products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the approval of other new therapies for the same indications;
- relative convenience and ease of administration of our product candidates; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and third-party payors, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for IGM-2323, our DR5 IgM antibody or future product candidates that we may develop. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We may seek Orphan Drug Designation for certain indications for our product candidates in the future. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Generally, if a product candidate with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. Therefore, if our competitors are able to obtain orphan product exclusivity for their product candidates in the same indications we are pursuing, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time. There are also limited circumstances where the FDA may reduce the seven-year exclusivity for a product candidate with an orphan drug designation where other product candidates show clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Historically, development of IgM antibodies has been limited by difficulties in recombinant expression and manufacture of these antibodies; therefore, the FDA may determine that we cannot assure the availability of sufficient quantities of our product candidates to the extent necessary to support marketing exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and approval standards. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If reimbursement is not available or is not sufficient for our products, it is less likely that our products will be widely used.

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Third-party payors, such as government healthcare programs, private health insurers and health maintenance organizations, decide which drugs they will cover and establish the level of reimbursement for such drugs. We cannot be certain that coverage and reimbursement will be available or adequate for any products that we develop. If coverage and adequate reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates, if approved.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future change to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors, including both government-funded and private payors, for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

If the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on therapeutic IgM antibodies for the treatment of cancer patients. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. If any of the foregoing estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. The FDA often approves new cancer therapies only for use after one or more other treatments have failed. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy or surgery, is sometimes adequate to treat the patient. If first-line therapy proves unsuccessful, second-line therapies, such as additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these therapies, may be administered. Third- or fourth-line therapies may include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We may initially seek approval of our product candidates for patients who have failed one or more approved treatments. For instance, in October 2019, we announced the dosing of the first patient in our Phase 1 clinical trial evaluating IGM-2323 for the treatment of relapsed/refractory B cell NHL patients. Even if we obtain regulatory approval and significant market share for IGM-2323, because the potential target population may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. In addition, there is no guarantee that any of our product candidates, even if approved, would be approved as a particular line of treatment. In addition, even if any of our product candidates were approved for a particular line of treatment, we may have to conduct additional clinical trials prior to gaining approval as an earlier line of treatment.

Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which will result in significant additional expense.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product.

For any approved product, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMPs and current good clinical practices (cGCP) for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the FDA's or comparable foreign 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, which would adversely affect our business, prospects and ability to generate revenue or achieve or sustain profitability.

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

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for any future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased regulatory scrutiny, including investigations by the FDA and other regulators of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;
- product recalls, a change in the indications for which they may be used or suspension or withdrawal of marketing approvals;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

We may need to have in place increased product liability coverage if and when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

Our product candidates, for which we intend to seek approval, may face competition sooner than anticipated.

Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." Under this statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full Biologics License Application (BLA) for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, efficacy and potency of their product. Furthermore, recent legislation has proposed that the 12-year exclusivity period for a referenced product may be reduced to seven years.

Acquisitions or joint ventures could increase our capital requirements, disrupt our business, cause dilution to our stockholders, cause us to incur debt or assume contingent liabilities and otherwise harm our business.

We evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with any strategic partners or suppliers as a result of such a transaction;
- the assumption of additional indebtedness or contingent or otherwise unanticipated liabilities related to acquired companies;
- the issuance of our equity securities;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals;
- increases in our expenses and reductions in our cash available for operations and other uses;
- 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; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. Future credit arrangements may restrict our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. Moreover, we may not be able to identify 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.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly those in the European Union, prescription drug pricing and reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

We will need to grow our organization, and we may experience difficulty in managing this growth, which could disrupt our operations.

As of September 30, 2019, we had 54 employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. Additionally, as our product candidates and discovery programs enter and advance through preclinical studies and any clinical trials, we will need to expand our development, manufacturing, regulatory and sales and marketing capabilities or contract with other organizations to provide these capabilities for us. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity amongst remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates and discovery programs. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend on our ability to effectively expand our organization and manage any future growth.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we or our CROs may collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by us. We manage and maintain our applications and data by utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. We face four primary risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our controls over the first three risks.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and that of any third-party billing and collections provider we may utilize, may be vulnerable to cybersecurity attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), mandatory notification and reporting obligations, additional regulatory oversight, significant regulatory penalties and remediation expenses. There is no guarantee that we can protect our systems from breach. Unauthorized access, loss or dissemination of information or any mechanical failure of our or our third-party service providers' information technology systems could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, the European Union, and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations vary between states, may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates, if approved, and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change healthcare systems in ways that could affect our ability to sell any of our product candidates profitably, if such product candidates are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the ACA was enacted, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the United States pharmaceutical industry. Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price (AMP), for most branded and generic drugs, respectively;
- Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- requirement that applicable manufacturers and group purchasing organizations report annually to the Centers for Medicare & Medicaid Services (CMS), information regarding certain payments and other transfers of value given to physicians and teaching hospitals, and any ownership or investment interest that physicians, or their immediate family members, have in their company;
- a requirement that manufacturers and authorized distributors of applicable drugs annually report information related to samples provided to practitioners;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- 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 & Medicaid Innovation at 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. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2027 unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 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. The Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers.

In the European Union similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. 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. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such products and third-party payors' reimbursement policies might adversely affect our ability to sell any future products profitably.

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business may be subject to risks associated with conducting business internationally. While we have not taken any steps to enter into any non-U.S. markets, we may do so in the future. In addition, our future suppliers and collaborative and clinical trial relationships may be located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes, including price controls;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing foreign operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research on product candidates and market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the Federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and applicable group purchasing organizations to report annually to CMS information related to "payments or other transfers of value" made to covered recipients, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and further that such applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members;
- analogous state and foreign 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 state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information relating to pricing and marketing information; and
- state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to be in violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Our employees, independent contractors, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants and vendors, could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a written code of business conduct and ethics, but it is not always possible to identify and deter employee or independent contractor misconduct, 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 comply with these laws or regulations. 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, including the imposition of significant fines or other sanctions.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing

laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the State of California to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Current or future laws and regulations may impair our research, development or commercialization efforts. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

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

Our operations, and those of our CROs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, failures or breaches of information technology systems, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

All of our operations including our corporate headquarters are located in a single facility in Mountain View, California. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. We do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.

We have incurred significant losses since our inception. Our net loss for the nine months ended September 30, 2019 and the year ended December 31, 2018 was \$28.3 million and \$22.7 million, respectively. As of September 30, 2019, our accumulated deficit was approximately \$92.4 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate product revenue or achieve profitability. For example, our expenses could increase if we are required by the FDA to perform clinical trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, developing our in-house manufacturing capabilities, hiring personnel, raising capital and providing general and administrative support for these operations. Since 2010, such activities have exclusively related to the research, development and manufacture of IgM antibodies and to building our proprietary IgM antibody technology platform. We are still in the early stages of developing our product candidates, and we have not completed development of any product candidate. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Our ability to generate revenue and achieve profitability depends in large part on our ability, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenue from sales of products for the foreseeable future.

To generate product revenue and become and remain profitable, we must succeed in developing and commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including:

- successfully completing preclinical and clinical development of our product candidates in a timely manner;
- obtaining regulatory approval for such product candidates in a timely manner;
- satisfying any post-marketing approval commitments required by applicable regulatory authorities;
- developing an efficient, scalable and compliant manufacturing process for such product candidates, including expanding and maintaining manufacturing operations, commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;
- successfully launching commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- maintaining a continued acceptable safety profile following any marketing approval;
- achieving commercial acceptance of such product candidates as viable treatment options by patients, the medical community and third-party payors;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio, including our licensed intellectual property;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidates; and
- attracting, hiring and retaining qualified personnel.

We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or operations.

All of our product candidates and discovery programs are in preclinical development or early stage clinical development. Developing drug products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates, which will increase our expenses. We will continue to require additional funding to complete the development and commercialization of our product candidates, to continue to advance our discovery programs, to expand our manufacturing facilities and to satisfy additional costs that we have incurred and expect to continue to incur in connection with operating as a public company. Such funding may not be available on acceptable terms or at all.

As of September 30, 2019, we had \$251.3 million in cash, cash equivalents and investments. On September 20, 2019, we closed our IPO, selling an aggregate of 12,578,125 shares of our common stock at \$16.00 per share. Proceeds from our IPO, net of underwriting discounts and commissions and offering expenses payable by us, were approximately \$183.0 million. We believe that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements into early 2022. Our estimate as to how long we expect the net proceeds from our IPO, together with our existing cash, cash equivalents and investments to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. In addition, because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the initiation, scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates, including expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and cost of capital expenditures to support our research, development and manufacturing efforts;
- the number and characteristics of other product candidates that we pursue;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
 - the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
 - the compliance and administrative costs associated with being a public company; and
 - the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public and private equity offerings, debt financings and strategic partnerships. We do not have any committed external source of funds. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our clinical or discovery programs or our business operations.

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available at all, may involve fixed payment obligations or agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through partnerships, collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our clinical or discovery programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. 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.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

At September 30, 2019, we had \$251.3 million of cash, cash equivalents and investments. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or investments since September 30, 2019, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and general economic downturn.

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

As of December 31, 2018, we had net operating loss (NOL) carryforwards available to reduce future taxable income, if any, for federal and California income tax purposes of approximately \$25.8 million and \$23.5 million, respectively. At December 31, 2018, we also had federal and California research and development tax credit carryforwards of \$2.5 million and \$1.9 million, respectively, available to offset future income tax, if any. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an “ownership change,” the corporation’s ability to use its NOLs and other pre-change tax attributes such as research tax credits to offset its post-change taxable income or taxes may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Although we have not yet completed a formal Section 382 study, we believe that we may have undergone an “ownership change” in the past and we may undergo one or more ownership changes as a result of future transactions in our stock. Consequently, we may be limited in our ability to use our NOL carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. As a result, even if we attain profitability, any limitations on the ability to use our NOL carryforwards and other tax assets could adversely affect our future cash flows. In addition, the Tax Cuts and Jobs Act of 2017 (Tax Act) imposes certain limitations on the deduction of NOLs, including a limitation on use of NOLs generated in tax years that began on or after January 1, 2018 to offset 80% of taxable income and disallowance of carryback of post-2017 NOLs.

Changes in the U.S. taxation of international business activities or the adoption of other tax reform policies could materially impact our business, results of operations and financial condition.

Changes to U.S. tax laws that may be enacted in the future could impact the tax treatment of our foreign earnings. If we expand our international business activities, any changes in the U.S. taxation of such activities may increase our worldwide effective tax rate and adversely affect our business, results of operations and financial condition. On December 22, 2017, President Trump signed into law the Tax Act, which significantly revises the Code. The Tax Act, among other things, reduces the corporate tax rate from a top marginal rate of 34% to a flat rate of 21%, repeals the alternative minimum tax for corporations, limits the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), eliminates U.S. tax on foreign earnings (subject to certain exceptions) and modifies or repeals many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”).

Risks Related to Our Dependence on Third Parties

We currently rely on third-party manufacturers to produce our product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.

We currently have limited in-house manufacturing experience and personnel. While we are in the process of designing and developing a cGMP manufacturing facility for the manufacture of clinical trial drug materials, we expect to continue to rely for some time on third parties to manufacture our product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards, and may do so for the commercial manufacture of some of our product candidates, if approved. To date, we have obtained bulk drug substance (BDS) for IGM-2323 from a single-source third-party contract manufacturer, and we expect to obtain BDS for our DR5 IgM antibody from a single-source third-party contract manufacturer as well. Any reduction or halt in supply of BDS from either of these contract manufacturers could severely constrain our ability to develop our product candidates until a replacement contract manufacturer is found and qualified. If we are unable to arrange for and maintain such third-party manufacturing sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. If we were to experience an unexpected loss of supply of our product candidates, for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Such failure or substantial delay or loss of supply could materially harm our business.

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

- the possible failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- reliance on the third party for regulatory compliance and quality control and assurance and failure of the third party to comply with regulatory requirements;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our product specifications);
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possibility of termination or nonrenewal of the agreement by the third-party at a time that is costly or damaging to us.

In addition, the FDA, EMA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. 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 marketing approval for or market our product candidates, if approved. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in sanctions being imposed on us, including fines, injunctions, civil penalties, restrictions on the product or on the manufacturing or laboratory facility, including license revocation, marketed product recall, suspension of manufacturing, product seizure, voluntary withdrawal of the product from the market, operating restrictions or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, would lead to a delay in, or failure to seek or obtain, regulatory approval of any of our product candidates. Furthermore, any change in manufacturer of our product candidates or approved products, if any, would require new regulatory approvals, which could delay completion of clinical trials or disrupt commercial supply of approved products.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts, or may miss expected deadlines, if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as contractually required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel.

If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA, EMA or other regulatory agencies.

Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCP regulations and guidelines enforced by the FDA, the competent authorities of the member states of the European Union and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA could determine that any of our clinical trials fail or have failed to comply with applicable cGCP regulations. In addition, our clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, and our clinical trials may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, our CROs are not required to work indefinitely or exclusively with us. Our existing agreements with our CROs may be subject to termination by the counterparty upon the occurrence of certain circumstances. If any CRO terminates its agreement with us, the research and development of the relevant product candidate would be suspended, and our ability to research, develop, and license future product candidates may be impaired. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us.

Switching or adding CROs or other suppliers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

We rely on third parties for various operational and administrative aspects of our business, including for certain cloud-based software platforms, which impact our financial, operational and research activities. If any of these third parties fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third party consultants and contractors to provide certain operational and administrative services. These services include tax advice and clinical and research consultation. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on “cloud-based” platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, and computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

Future strategic partnerships may be important to us. We will face significant competition in seeking new strategic partners.

We have limited capabilities for drug development and manufacturing and do not yet have any capability for sales, marketing or distribution. For some of our product candidates, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. The competition for strategic partners is intense. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the strategic partner’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner’s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The strategic partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such collaboration could be more attractive than the one with us for our product candidate.

Strategic partnerships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Even if we are successful in entering into collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements with other potential collaborators.

If we are unable to reach agreements with suitable strategic partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our therapeutic platforms and our business may be materially and adversely affected. Any collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the partner terminates the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, and increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches the market.

If we are unable to maintain future strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected.

Any future strategic partnerships we enter into may pose a number of risks, including the following:

- we may not be able to enter into critical strategic partnerships or enter them on favorable terms;
- strategic partners have significant discretion in determining the effort and resources that they will apply to such a partnership, and they may not perform their obligations as agreed or expected;
- strategic partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- strategic partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- strategic partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates;
- product candidates discovered in collaboration with us may be viewed by our strategic partners as competitive with their own product candidates or products, which may cause strategic partners to cease to devote resources to the commercialization of our product candidates;
- a strategic partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidates;
- disagreements with strategic partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- strategic partners 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 potential litigation;
- strategic partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- strategic partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Risks Related to Our Intellectual Property

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. 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 future approved products or impair our competitive position.

Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. We are aware of third party patents and patent applications containing claims directed to most of our areas of product development, which patents and applications could potentially be construed to cover our product candidates and the use thereof to treat cancer patients. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that there are not third-party patents or patent applications of which we are aware, but which we do not believe are relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. These patents may not expire before we receive marketing authorization for our product candidates, and they could delay the commercial launch of one or more future products. If our products were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms, or at all, our business, financial condition and results of operations could be materially harmed. Furthermore, even if a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Our failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations, and we would be exposed to a threat of litigation.

In the biotechnology industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace both within and outside the United States including patent infringement lawsuits, oppositions, *inter partes* review (IPR) and post-grant review (PGR) proceedings before the United States Patent and Trademark Office (USPTO), or the applicable foreign patent counterpart. The types of situations in which we may become a party to such litigation or proceedings include:

- we may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties, to obtain a judgment that our products or processes do not infringe those third parties' patents or to obtain a judgment that those parties' patents are unenforceable;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights or initiate other proceedings, including post-grant proceedings such as oppositions, IPRs or PGRs, we will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or on our business, results of operations, financial condition and prospects. Any of these outcomes could have a material adverse effect on our business.

If we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed.

Our strategy depends on our ability to identify, seek, obtain and maintain patent protection for our discoveries. As of September 30, 2019, our patent portfolio included six granted patents, 132 pending applications in active prosecution in 16 countries or regions, three pending Patent Cooperation Treaty (PCT) applications, and eight pending unpublished provisional applications. Our patent portfolio is relatively small compared to many large and more established pharmaceutical and biotechnology companies that have patent portfolios consisting of hundreds, and in some case even thousands, of granted patents. As our patent portfolio grows, we expect patent protection will continue to be an important part of our strategy. The patent protection process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, 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 have licensed from third parties. Therefore, our owned or in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issues from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries or that effectively prevent third parties from commercializing competitive product candidates.

Moreover, the patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. We may be subject to a third-party preissuance submission of prior art to the USPTO or a foreign jurisdiction, and such prior art may affect the scope of any claims we ultimately get allowed or it may prevent our patent applications from issuing as patents. Further, the issuance of a patent does not ensure that it is valid or enforceable, nor is the issuance conclusive as to inventorship or the scope of any claims. Third parties may challenge the validity, enforceability or scope of our issued patents or claim that they should be inventors on such patents, and such patents may be narrowed, invalidated, circumvented, or deemed unenforceable and such third parties may gain rights to such patents. We could also become involved in reexamination, *inter partes* review, post-grant review, opposition or derivation proceedings, challenging our patent rights or the patent rights of others. In addition, changes in law may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. If, our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Our intellectual property rights will not necessarily provide us with competitive advantages.

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- 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;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful.

Third parties may seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for an invalidity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition, IPR or PGR proceedings challenging the validity or scope of our patent rights, requiring us and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us under the Biologics Price Competition and Innovation Act of 2009, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. Adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed or trade secrets not misappropriated by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents or trade secrets could limit our ability to assert our patents or trade secrets against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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 an adverse effect on the price of our common stock.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain protection under the Hatch-Waxman amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective 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 also may be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. For example, we treat our proprietary computational technologies, including unpatented know-how and other proprietary information, as trade secrets. Trade secrets and know-how can be difficult to protect. Trade secrets and know-how can also in some instances be independently derived or reverse-engineered by a third party. We maintain the confidentiality of trade secrets and proprietary information, in part by entering into confidentiality agreements with our employees, consultants, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and even when we obtain these agreements, individuals with whom we have these agreements may not comply with their terms. Any of the parties to these agreements may breach such agreements and disclose our proprietary

information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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 also become involved in inventorship disputes relating to inventions and patents developed by our employees or consultants under such agreements. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. 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 third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

We employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, 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 such claims, in addition to paying monetary damages, trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such license may not be available on commercially reasonable terms or at all. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees automatically when due, but we must notify the provider of any new patents or applications. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

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

Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents, we may in the future be subject to claims that former employees, strategic partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent protection and patent prosecution for some of our product candidates may be dependent on, and the ability to assert patents and defend them against claims of invalidity may be maintained by, third parties.

There may be times in the future when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers.

If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents or in third-party patents. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened 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 validity, scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act (AIA), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or does file a patent application in the USPTO after March 16, 2013 but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to file third party submissions of prior art to the USPTO during patent prosecution and to challenge any issued patent in the USPTO (e.g., via post-grant reviews or *inter partes* reviews). This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the 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 current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Recent United States Supreme Court cases have narrowed the scope of what is considered patentable subject matter, for example, in the areas of software and diagnostic methods involving the association between treatment outcome and biomarkers. This could impact our ability to patent certain aspects of our technology in the United States.

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

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status, and patenting of medical uses of a claimed drug are prohibited. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names and potential pharmacy dispensing errors. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Some of our discovery programs include antibodies that are licensed from third parties pursuant to limited research licenses. If we decide to further develop or commercialize these discovery programs as future product candidates, we may need to exercise our option to enter into a commercial license with one or more of these third parties. If we are unable to successfully enter into those commercial licenses or if we breach the terms of our existing research licenses or future commercial licenses, we would not have the ability to continue the development and potential commercialization of such discovery programs.

We have in-licensed certain antibodies for our discovery programs from third parties. Under these license agreements, we are able to research and initially develop discovery programs and are required to make certain annual payments. We also have the option to negotiate or enter into commercial license agreements with these third parties if we elect to continue development or commercialization of any product candidates incorporating the in-licensed antibodies. If we exercise our option to negotiate or enter into any commercial licenses with these third parties, we will likely be subject to various additional obligations, which may include obligations with respect to funding, development and commercialization activities, and payment obligations upon achievement of certain milestones and royalties on product sales. If any of our existing antibody research licenses or future commercial licenses are terminated or breached, we may:

- lose our rights or options to research, develop or commercialize certain of our future product candidates;
- not be able to secure patent or trade secret protection for certain of our future product candidates;
- experience significant delays in the development or commercialization of certain of our future product candidates;
- not be able to obtain other licenses that may allow us to continue to progress the applicable programs on acceptable terms, if at all; or
- incur liability for damages.

Additionally, even if not terminated or breached, our intellectual property licenses may be subject to disagreements over contract interpretation which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations. If we experience any of the foregoing, it could have a materially adverse effect on our business.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile, which could result in substantial losses for investors.

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to those discussed in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- results and timing of our preclinical studies and clinical trials and studies and trials of our competitors’ products;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors’ products;
- competition from existing products or new products that may emerge;
- actual or anticipated changes in our growth rate relative to our competitors;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- actual or anticipated changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;

- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- announcements or expectations of additional financing efforts;
- general market conditions and market conditions for biotechnology stocks;
- overall fluctuations in U.S. equity markets; and
- other factors that may be unanticipated or out of our control

The stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stock often does not relate to the operating performance of the companies presented by the stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

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

Prior to the closing of our IPO in September 2019, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active market trading market for our common stock may not be sustained in the future. The lack of an active trading market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the market value of their shares, may impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

We are controlled by Haldor Topsøe Holding A/S and a concentrated group of stockholders, whose interests in our business may conflict with yours.

As of September 30, 2019, Haldor Topsøe Holding A/S (HTH), together with other holders of 5% or more of our outstanding capital stock and their respective affiliates, beneficially owned approximately 24,801,117 shares, or 81.2%, of our outstanding capital stock (which includes 18,369,912 shares, or 76.2%, of our voting common stock). Accordingly, our principal stockholders will be able to control most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, including mergers and sales of all or substantially all of our assets. The interests of these principal stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders. For example, our concentration of ownership could have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could cause the market price of our common stock to decline or prevent our stockholders from realizing a premium over the market price for their shares of our common stock.

In addition, pursuant to nominating agreements entered into between us and each of (i) HTH, (ii) Baker Brothers Life Sciences L.P. and 667, L.P. (together, Baker Brothers) and (iii) Redmile Biopharma Investments II, L.P., RAF, L.P. and Redmile Strategic Master Fund, LP (together, Redmile), for up to 12 years following the completion of our IPO, so long as HTH, Baker Brothers and Redmile, together with their respective affiliates, each beneficially own certain specified amounts of our capital stock, we will have the obligation to support the nomination of, and to cause our board of directors to include in the slate of nominees recommended to our stockholders for election, (i) two individuals designated by HTH, (ii) one individual designated by Baker Brothers and (iii) one individual designated by Redmile, subject to certain customary conditions and exceptions. Each of HTH, Baker Brothers and Redmile, and their respective affiliates, may therefore have influence over management and control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation as currently in effect. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

A significant portion of our total outstanding common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of our common stock in the public market could occur in the future. These sales, upon the expiration of the market standoff and lock-up agreements, or the perception in the market that the holders of a large number of common stock intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise additional capital through the sale of equity securities in the future. As of September 30, 2019, we had an aggregate of 30,535,899 outstanding shares of common stock and non-voting common stock. Of these shares, the 12,578,125 shares sold in our IPO may be resold in the public market immediately, unless purchased by our affiliates. Of the remaining shares, 17,957,774 shares of our common stock are currently restricted under securities laws or as a result of market standoff and lock-up agreements; however, subject to applicable securities law restrictions and excluding shares of restricted stock that will remain unvested, these shares will be able to be sold in the public market beginning as early as 180 days following the effectiveness of the registration statement on Form S-1 related to our IPO.

In addition, on September 18, 2019, we filed a registration statement on Form S-8 to register 5,248,639 shares of our common stock reserved for future issuance under our equity compensation plans. As a result, shares registered under this registration statement on Form S-8 will be available for sale in the public market subject to the satisfaction of applicable vesting arrangements and the exercise of such options, the lock-up arrangements described above and, in the case of our affiliates, the restrictions of Rule 144.

Moreover, as of September 30, 2019, certain holders of approximately 25,287,260 shares of our common stock (including common stock issuable upon conversion of our non-voting common stock) have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Our executive officers, directors and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into market stand-off agreements with us and lock-up agreements with the underwriters in our IPO under which they have agreed, subject to specific exceptions, not to sell, directly or indirectly, any shares of common stock without the permission of the underwriters for a period of 180 days following the effectiveness of the registration statement on Form S-1 related to our IPO. We refer to such period as the lock-up period. When the lock-up period expires, we and our securityholders subject to a lock-up agreement or market stand-off agreement will be able to sell our shares in the public market. In addition, the representatives of the underwriters may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Sales of a substantial number of such shares upon expiration of the lock-up and market stand-off agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate. Even if a substantial number of sales of our common stock does not occur, the mere perception of the possibility of these sales could depress the market price of our common stock and have a negative effect on our ability to raise capital in the future.

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

The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock, our share price would likely decline. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act) or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. We have identified deficiencies in the past which we have taken steps to address. However, our efforts to remediate previous deficiencies may not be effective or prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

In connection with our evaluation of our internal controls over financial reporting, we expect to upgrade our finance and accounting systems. If we are unable to accomplish these objectives in a timely and effective manner, our ability to comply with the financial reporting requirements and other rules that apply to reporting companies could be adversely impacted. Any failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition and results of operations and the trading price of our common stock.

As a public company, we are required to disclose material changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Beginning with our annual report on Form 10-K for the year ending December 31, 2020, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act), our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404.

To achieve compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and maintain a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and continue to implement a continuous reporting and improvement process for internal control over financial reporting.

An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. In addition, our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, 2017 or December 31, 2018 in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed such an evaluation, control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to corporate governance standards.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” Our management and other personnel have devoted and will continue to devote a substantial amount of time and incur substantial expense in connection with compliance initiatives. For example, in anticipation of becoming a public company, we adopted additional internal controls and disclosure controls and procedures, retained a transfer agent and adopted an insider trading policy. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the SEC, and the Nasdaq Stock Market LLC (Nasdaq), have and will continue to increase legal and financial compliance costs and make some compliance activities more time consuming. We cannot predict or estimate the amount of additional costs we may incur to respond to these requirements or the timing of such costs. We have invested and will continue to invest in resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under the corporate governance standards of Nasdaq, a majority of our board of directors and each member of our audit committee must be an independent director no later than the first anniversary of the completion of our IPO. We may encounter difficulty in attracting qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common stock from the Nasdaq Global Select Market.

We are an “emerging growth company,” and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an “emerging growth company” until the earliest to occur of: the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue, the date we qualify as a “large accelerated filer,” with the market value of our common stock held by non-affiliates exceeding \$700 million as of June 30, the issuance by us of more than \$1.0 billion of non-convertible debt over a three-year period, and the last day of the fiscal year ending after the fifth anniversary of our IPO, or December 31, 2024. Investors could find our common stock less attractive if we choose to rely on these exemptions. 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. We have elected to use this extended transition period until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates. If some investors find our common stock less attractive as a result of any of our reliance on these exemptions, there may be a less active trading market for our common stock and our share price may be more volatile.

We have never paid and do not anticipate paying cash dividends on our common stock, and accordingly, stockholders must rely on share appreciation for any return on their investment.

We have never paid any dividends on our capital stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and do not anticipate that we will declare or pay any cash dividends on our capital stock in the foreseeable future. See the section titled “Dividend Policy.” As a result, capital appreciation, if any, of our common stock will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of convertible preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding under Delaware statutory or common law brought on our behalf;
- any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. This exclusive-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 lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. If a court were to find this exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Nothing in our amended and restated bylaws precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

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

Unregistered Sales of Equity Securities

In April 2019, we issued and sold 7,566 shares of our common stock to the heir of a former service provider in consideration of proceeds of \$500 and cancellation of an option to the service provider.

In July 2019, we issued and sold 3,026,449 shares of our Series C convertible preferred stock to five accredited investors for aggregate proceeds of approximately \$40.0 million.

From July 1, 2019 through September 18, 2019 (the date of the filing of our registration statement on Form S-8), we granted stock options to purchase an aggregate of 342,766 shares of our common stock to certain directors, officers, employees, consultants and other service providers under the 2018 Plan.

From July 1, 2019 through September 18, 2019 (the date of the filing of our registration statement on Form S-8), we issued and sold to an employee 3,329 shares of our common stock upon the exercise of an option under our 2018 Plan at an exercise price per share of \$1.39, for an aggregate exercise price of approximately \$4,620.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales and issuances of the securities described above were exempt from registration under the Securities Act (or Regulation D or Regulation S promulgated thereunder) by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering, or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The recipients of such securities, other than the recipients of shares of Series C convertible preferred stock, were our employees, consultants or directors and they received the securities under our 2018 Plan. Each recipient of shares of Series C convertible preferred stock was an accredited investor. The recipients of the securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds from Public Offering of Common Stock

On September 17, 2019, our registration statement on Form S-1 (File No. 333-2233365) was declared effective by the SEC for our initial public offering of common stock. We began trading on the Nasdaq Global Select Market on September 18, 2019, and the transaction formally closed on September 20, 2019. In connection with our IPO, we issued and sold an aggregate of 12,578,125 shares of our common stock at a price of \$16.00 per share, including 1,640,625 shares issued and sold in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock. The aggregate offering price for shares sold in our IPO was \$201.3 million. The joint book-running managers for the initial public offering were Jefferies LLC, Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated. After deducting underwriting discounts and commissions and offering costs paid or payable by us of approximately \$18.4 million, the net proceeds from the offering were approximately \$183.0 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our director compensation policy.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on September 18, 2019 pursuant to Rule 424(b)(4). We invested the funds received in interest-bearing investment-grade securities.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39045	3.1	September 20, 2019
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-39045	3.2	September 20, 2019
4.1	Specimen common stock certificate of the Registrant.	S-1/A	333-233365	4.1	September 3, 2019
10.1+	Amended and Restated 2018 Omnibus Incentive Plan and forms of agreements thereunder.	S-1/A	333-233365	10.3	September 3, 2019
10.2+	2019 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	333-233365	10.4	September 3, 2019
10.3+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1/A	333-233365	10.5	September 3, 2019
10.4+	Confirmatory Employment Letter, by and between Fred Schwarzer and the Registrant, effective as of August 19, 2019.	S-1	333-233365	10.6	August 19, 2019
10.5+	Confirmatory Employment Letter, by and between Bruce Keyt and the Registrant, effective as of August 19, 2019.	S-1	333-233365	10.9	August 19, 2019
10.6+	Confirmatory Employment Letter, by and between Misbah Tahir and the Registrant, effective as of August 19, 2019.	S-1	333-233365	10.10	August 19, 2019
10.7+	Change in Control and Severance Policy.	S-1	333-233365	10.11	August 19, 2019
10.8+	Outside Director Compensation Policy	S-1/A	333-233365	10.12	September 3, 2019
10.9+	Executive Incentive Compensation Plan.	S-1	333-233365	10.13	August 19, 2019
31.1	Certification of Principal 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.				
31.2	Certification of Principal 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.				
32.1†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

+ Indicates management contract or compensatory plan.

† The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant 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 Quarterly Report on 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 thereunto duly authorized.

IGM Biosciences, Inc.

Date: November 7, 2019

By: _____
/s/ Fred Schwarzer
Fred Schwarzer
*Chief Executive Officer and President
(Principal Executive Officer)*

Date: November 7, 2019

By: _____
/s/ Misbah Tahir
Misbah Tahir
*Chief Financial Officer
(Principal Financial and Accounting Officer)*

**CERTIFICATION 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, Fred Schwarzer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of IGM 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2019

By: _____
/s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer and President
(Principal Executive Officer)

**CERTIFICATION 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, Misbah Tahir, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of IGM 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2019

By: _____
/s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

PURSUANT TO

**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of IGM Biosciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fred Schwarzer, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 7, 2019

By: _____
/s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer and President
(Principal Executive Officer)

In connection with the Quarterly Report of IGM Biosciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Misbah Tahir, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 7, 2019

By: _____
/s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer
(Principal Financial and Accounting Officer)