Table of Contents

As filed with the Securities and Exchange Commission on September 22, 2020.

Registration No. 333-

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

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

UNUM THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**46-5308248**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

200 CambridgePark Drive, Suite 2500
Cambridge, Massachusetts 02140
(617) 945-5576
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Charles Wilson
Chief Executive Officer and President
Unum Therapeutics Inc.
200 CambridgePark Drive, Suite 2500
Cambridge, Massachusetts 02140
(617) 945-5576
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:

Kingsley L. Taft, Esq.
Danielle Lauzon, Esq.
Goodwin Procter LLP
100 Northern Avenue
Boston, Massachusetts 02210
(617) 570-1000

Approximate date of commencement of proposed sale to the public:
From time to time after this registration statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common Stock, par value $0.001 per share	169,530,903			
Total	169,530,903	$2.915	$494,182,582.25	$64,144.90

(1) Represents shares offered by the selling stockholders, consisting of 6,235,903 shares of common stock, par value $0.001 per share, and 163,295,000 shares of common stock issuable upon conversion of an aggregate of 163,295 shares of Series A Non-Voting Convertible Preferred Stock, par value $0.001 per share. Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, or the Securities Act, this registration statement also covers such additional shares as may hereafter be offered or issued to prevent dilution resulting from stock splits, stock dividends, recapitalizations or certain other capital adjustments.

(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) of under the Securities Act. The price per share and aggregate offering price are based on the average of the high and low prices of the registrant's shares of common stock on September 18, 2020, as reported on The Nasdaq Global Select Market.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that the registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. The selling shareholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, Dated September 22, 2020

PROSPECTUS

169,530,903 Shares
Common Stock
Offered by the Selling Shareholders

This prospectus relates to the proposed resale or other disposition by the selling shareholders identified herein, or the Selling Shareholders, of (i) 6,235,903 shares of our common stock, par value $0.001 ("Common Stock" and such shares the "Merger Common Shares"), (ii) 44,657,000 shares of our Common Stock issuable upon the conversion of 44,657 shares of the Series A Non-Voting Convertible Preferred Stock, par value $0.001 ("Series A Preferred Stock" and such shares the "Merger Series A Shares") and (iii) 118,638,000 shares of our Common Stock issuable upon the conversion of 118,638 shares of the Series A Preferred Stock ("Converting Shares", and together with the Merger Common Shares and Merger Series A Shares, "Shares"). The Merger Series A Shares and the Converting Shares will be convertible to Common Stock pursuant to the terms of a certificate of designation of preferences, right and limitations of Series A Non-Voting Convertible Preferred Stock and only upon approval by our stockholders of a stock split of all outstanding shares of Common Stock.

The Merger Common Shares and Merger Series A Shares being offered were issued and sold to accredited investors in connection with an acquisition, or the Merger, which closed on July 6, 2020. The Converting Shares being offered were issued and sold to accredited investors in a private placement, or the 2020 Private Placement, which closed on July 9, 2020. We are not selling any Shares under this prospectus and will not receive any of the proceeds from the sale or other disposition of Shares by the Selling Shareholders.

The Selling Shareholders may sell the Shares on any national securities exchange or quotation service on which the securities maybe listed or quoted at the time of sale, on the over-the-counter market, in one or more transactions otherwise than on these exchanges or systems, such as privately negotiated transactions, or using a combination of these methods, and at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. See the disclosure under the heading "Plan of Distribution" elsewhere in this prospectus for more information about how the Selling Shareholders may sell or otherwise dispose of their Shares hereunder.

The Selling Shareholders may sell any, all or none of the securities offered by this prospectus and we do not know when or in what amount the selling shareholders may sell their Shares hereunder following the effective date of the registration statement of which this prospectus forms a part.

You should carefully read this prospectus and the applicable prospectus supplement, as well as any documents incorporated by reference, before you invest in any of the securities being offered.

Our Shares are listed on The Nasdaq Global Select Market under the symbol "UMRX." On September 21, 2020, the closing price for our Shares, as reported on The Nasdaq Global Select Market, was $2.85 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties referenced under the heading "Risk Factors" contained in this prospectus beginning on page 7 and any applicable prospectus supplement, and under similar headings in the other documents that are incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2020.

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under this shelf registration process, the Selling Shareholders may, from time to time, sell the securities described in this prospectus in one or more offerings.

Neither we, nor the Selling Shareholders, have authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You should rely only on the information contained in or incorporated by reference in this prospectus. The Selling Shareholders are offering to sell, and seeking offers to buy, our securities only in jurisdictions where it is lawful to do so. We have not authorized anyone to provide you with different information. This prospectus and any accompanying prospectus supplement do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in any accompanying prospectus supplement or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, any prospectus supplement, the documents incorporated by reference and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

Unless the context otherwise requires, we use the terms "Unum," "company," "we," "us," and "our" in this prospectus to refer to Unum Therapeutics Inc. and, where appropriate, our subsidiary.

This prospectus contains trade names, trademarks and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or TM symbols.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "continue," and similar expressions, or the negative of these terms, or similar expressions. Accordingly, these statements involve estimates, assumptions, risks and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors referenced in the section "Risk Factors."

This prospectus contains forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. These statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the effects of our recently-initiated restructuring, including a substantial reduction in our workforce to reduce our operating costs;
- the potential impacts of raising additional capital, including dilution to our existing stockholders, restrictions on our operations or requirements that we relinquish rights to our technologies or product candidates;
- business interruptions resulting from the coronavirus disease (COVID-19) outbreak or similar public health crises, which could cause a disruption of the development of our product candidates and adversely impact our business;
- the success, cost, and timing of our product development activities and clinical trials;
- the timing of our planned IND submission to the FDA for our product candidate for PLX9486;
- our ability to obtain and maintain regulatory approval for our PLX9486 product candidates and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the potential for our identified research priorities to advance our PLX9486 platform;
- the ability to license additional intellectual property relating to our product candidates from third-parties and to comply with our existing license agreements and collaboration agreements;
- the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates;
- our ability to commercialize our products in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the scalability and commercial viability of our manufacturing methods and processes;
- the commercialization of our product candidates, if approved;
- our plans to research, develop, and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory, and commercialization expertise;

- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our use of the proceeds from the initial public offering, the Concurrent Private Placement and the Series A Preferred Stock as defined herein;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; and
- other risks and certainties, including those listed under the caption entitled “Risk Factors.”

These forward-looking statements are neither promises nor guarantees of future performance due to a variety of risks and uncertainties and other factors more fully discussed in the “Risk Factors” section in this prospectus, the section of any accompanying prospectus supplement entitled “Risk Factors” and the risk factors and cautionary statements described in other documents that we file from time to time with the SEC which are incorporated by reference herein. Given these uncertainties, readers should not place undue reliance on our forward-looking statements. These forward-looking statements speak only as of the date on which the statements were made and are not guarantees of future performance. Except as may be required by applicable law, we do not undertake to update any forward-looking statements after the date of this prospectus or the respective dates of documents incorporated by reference herein or therein that include forward-looking statements.

PROSPECTUS SUMMARY

Overview

On July 6, 2020, we completed our acquisition of Kiq Bio LLC (formerly Kiq LLC), a Delaware limited liability company ("Kiq"), in accordance with the terms of the Agreement and Plan of Merger, dated July 6, 2020 ("Merger Agreement").

Through this acquisition of Kiq, we are now a biopharmaceutical company focused on developing a pipeline of novel therapies to treat cancer patients. Our most advanced program, PLX9486, is a clinical-stage, highly potent and selective KIT D816V inhibitor that is being developed to treat systemic mastocytosis and Gastrointestinal Solid Tumor (GIST) patients. PLX9486 has been administered to more than 50 advanced solid tumor and GIST patients in a Phase 1 / 2 clinical trial, with the vast majority of those patients living with advanced GIST. GIST is a disease frequently driven by mutations in the KIT tyrosine kinase, and resistance to therapy can be seen with the emergence of new KIT mutations. Anti-tumor activity for PLX9486 was observed in both single agent and combination settings, including in combination with sunitinib, an approved treatment option for GIST patients. Clinical data for PLX9486 were previously presented by Plexxikon, a member of the Daiichi Sankyo Group, at the Connective Tissue Oncology Society meeting in November 2017, and the American Society of Clinical Oncology meeting in June 2018.

On July 6, 2020, we shared updated clinical data in 18 patients dosed with PLX9486 in combination with sunitinib as part of our corporate presentation describing the Kiq acquisition, showing median progression free survival of eleven months. This was a heavily-treated advanced GIST population, where 72 percent of patients had previously been treated with sunitinib, 66 percent of patients had received three-or-more Tyrosine kinase inhibitors (TKIs), and 50 percent of patients had received four-or-more TKIs. The overall response rate was 16.6 percent, including two partial responses and one complete response.

Based on these results, we plan to meet with the FDA to explore further clinical development of PLX9486 in combination with sunitinib in GIST patients, and plan to initiate an additional clinical study in GIST in the second half of 2021.

In addition to continuing the development of PLX9486 in GIST patients, we are pursuing development of the compound in patients living with advanced systemic mastocytosis (ASM) and indolent systemic mastocytosis (ISM). Systemic mastocytosis is a disease almost entirely defined by KIT D816V, and patients with ASM have a significantly diminished quality of life and median survival of less than approximately 3.5 years. For patients with ISM, there are no available approved therapies, and while their lifespan is not shortened by the disease, these patients suffer from a poor quality of life and new treatment options are badly needed. Emerging clinical data for other kinase inhibitors with activity against KIT D816V have shown that the disease is highly sensitive to inhibition of the target. PLX9486 was specifically designed to selectively inhibit KIT mutations on exon 17, including KIT D816V, and we aim to expand the clinical development of this program to treat systemic mastocytosis patients.

Subject to feedback from regulatory authorities, we expect to initiate clinical trials in ASM patients in the first half of 2021, followed by trials in ISM patients in the second half of 2021. We expect to rapidly assess PLX9486 activity in mastocytosis patients by monitoring levels of serum tryptase, a relevant biomarker of disease activity which is elevated in these patients.

Worldwide rights to develop and commercialize PLX9486, as well as an additional selective KIT inhibitor, PLX0206, were exclusively licensed by Kiq from Plexxikon. Under the terms of the May 2020 agreement,

Plexxikon received an upfront payment and is eligible for additional development milestones and mid- to high- single-digit royalty payments. Plexxikon has also committed to a transition plan to enable the seamless transfer of the program.

Patents protecting PLX9486 include composition of matter claims which have issued in the US and other key territories and provide exclusivity through 2033 and potentially beyond.

In March 2020, we announced that we would be suspending further clinical testing of all Antibody-Coupled T cell Receptor (ACTR) product candidates and focusing efforts on advancing our Bolt-On Chimeric Receptor (BOXR) platform with the aim of bringing the lead BOXR product candidate, BOXR1030, into clinical testing. With the acquisition of Kiq and the focus on development of novel precision kinase inhibitors, we are directing our legacy cell therapy efforts towards the identification of an external partner who will have responsibility for future development of the technology and development of product candidates. In August 2020, the BOXR platform was sold to SOTIO for an upfront payment of $8.1 million ($1.725 million of which was placed in escrow for 90 days) with potential downstream milestones of up to $3.4 million.

All ACTR clinical trials are closed to further enrollment. We anticipate completing all closeout activities of 3 of 4 ACTR clinical trials by the end of the quarter ending September 30, 2020. We are initiating a study closeout plan for the fourth clinical trial and anticipate closing out the last ACTR clinical trial in the first half of 2021.

Corporate Information

We were incorporated under the laws of the State of Delaware in March 2014. Our principal executive office is located at 200 CambridgePark Drive, Suite 2500, Cambridge, Massachusetts 02140, and our telephone number is (617) 945-5576. Our website address is *www.unumrx.com*. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the

date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission (SEC). We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We have irrevocably elected to "opt out" of the exemption for the delayed adoption of certain accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below and all other information contained or incorporated by reference into this prospectus, as updated by our subsequent filings under the Exchange Act, and the risk factors and other information contained in the applicable prospectus supplement before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. Our business, financial condition or results of operations could be materially adversely affected by the materialization of any of these risks. The trading price of our securities could decline due to the materialization of any of these risks, and you may lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations.

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in March 2014. Our net losses were $7.4 million and $10.5 million for the three months ended June 30, 2020 and 2019 and $13.5 million and $22.2 million for the six months ended June 30, 2020 and 2019. As of June 30, 2020, we had an accumulated deficit of $137.4 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, product candidates.

As of December 31, 2019, we had identified conditions and events that raise substantial doubt about our ability to continue as a going concern. As of December 31, 2019, management had assessed this risk in accordance with the requirements of Accounting Standards Update, or ASU, No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Accounting Standards Codification, or ASC, Subtopic 205-40), or ASC 205-40. Based on our recurring losses and cash outflows from operations, since our inception, an expectation of continuing operating losses and cash outflows from operations for the foreseeable future, and the removal of revenues generated under the Collaboration Agreement with Seattle Genetics as a result of the termination of that Agreement, we had concluded that there is substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. As of June 30, 2020, we had cash and cash equivalents of $21.3 million. We expect that our current cash and cash equivalents, including the $104.4 million we received on July 9, 2020 from the Series A Preferred Stock private placement, will be sufficient to fund our operating expenses and capital expenditure requirements beyond 2022.

There can be no assurance that the products under development by us will be approved for sale in the United States or elsewhere. Furthermore, there can be no assurance that if such products are approved, they will be successfully commercialized, which would have an adverse effect on our business prospects, financial condition and results of operation.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown

factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We may require substantial additional funding. If we fail to obtain additional financing when needed, or on attractive terms, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. As of June 30, 2020, we had working capital of $15.7 million and capital resources consisting of cash and cash equivalents of $21.3 million. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, including our planned clinical trials for PLX9486. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

Our operating plan includes our efforts to advance our clinical programs for PLX9486, for the treatment of systemic mastocytosis (SM) and Gastrointestinal Stromal Tumors (GIST); to fund the wind down of ACTR707 used in combination with rituximab for adult patients with r/r B cell non-Hodgkin lymphoma, ACTR087 used in combination with rituximab for adult patients with r/r non-Hodgkin lymphoma, in 2019, and ACTR707 used in combination with trastuzumab for patients with HER2+ cancers; and to develop product candidates in earlier stages of development, and any additional product candidates that we select, to expand headcount and internal capabilities, and for working capital and other general corporate purposes. We will need to raise additional funds to progress into clinical development any additional product candidates that we may select. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. 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 may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

We may expend our limited resources to pursue a particular product candidate or indication, or platform technology, and fail to capitalize on product candidates or indications or platform technology that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable programs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Related to the Discovery and Development of Our Drug Candidates

Our business is highly dependent on the success of our future PLX9486 programs for the treatment of SM and GIST and any other potential product candidates that we develop.

Our business and future success depend on our ability to obtain regulatory approval of and then successfully commercialize our PLX9486 program and other product candidates that we develop. All of our product candidates are in the early stages of development and will require additional preclinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales.

Clinical trials are expensive, time-consuming, and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. We are unable to predict when or if our drug or any of our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim or preliminary results of a clinical trial do not necessarily predict final results, and results for one indication may not be predictive of the success in additional indications. In particular, the small number of patients in our early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy, or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug or drug candidates, including:

- regulators may not authorize us to commence or continue a clinical trial or may impose a clinical hold or may limit the conduct of a clinical trial through the imposition of a partial clinical hold;
- institutional review boards (IRBs) may not authorize us or our investigators to commence or continue a clinical trial at a prospective trial site or an IRB may not approve a protocol amendment to an ongoing clinical trial;

- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay planned trials, or abandon product development programs;
- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, or the duration of these clinical trials may be longer than we anticipate;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, due to interruptions to their business or may fail to comply with regulatory requirements;
- we may have to suspend, change, or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- our drug or drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or IRBs to suspend, change, or terminate the trials;
- unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as COVID-19, in or around the countries in which we conduct our clinical trials or where our third-party contractors operate, could delay the commencement or rate of completion of our clinical trials;
- the cost of clinical trials for our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug or drug candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials.

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured, or will be completed on schedule, or at all. Our ongoing trials continue to generate additional data that may be requested by the FDA. The FDA may request additional information or data and any such requests could result in clinical trial delays. Furthermore, the FDA could place a clinical hold, either another partial clinical hold or a full clinical hold, on our trials if they are not satisfied with the information we provide to them, which could result in delays for the trial. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

We may utilize companion diagnostics in our planned clinical trials in the future in order to identify appropriate patient populations. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Since the number of patients that we have dosed in our Phase 1 clinical trials is small, the results from such clinical trials may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

A study design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the

impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we may have seen in prior clinical trials. Additionally, our inability to dose a sufficient number of patients in our clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the perceived risks and benefits of our product candidate in the trial;
- reporting of the preliminary results of any of our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. 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 will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, may be interpreted differently if additional data are disclosed, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which may be based on a preliminary analysis of then-available data in a summary or "top-line" format, and the results

and related findings may change as more patient data become available, may be interpreted differently if additional data are disclosed at a later time and are subject to audit and verification procedures that could result in material changes in the final data. If additional results from our clinical trials are not viewed favorably, our ability to obtain approval for and commercialize our drug candidates, our business, operating results, prospects, or financial condition may be harmed and our stock price may decrease.

We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been disclosed and/or are received and fully evaluated. Such data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary and "top-line" data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product, and our business in general. Additionally, our Phase 1 /2 clinical trial of PLX9486 was an open-label trial and future trials we may conduct may be open-label trials. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include those patients with the most severe symptoms, which may have improved notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

We may not be able to file investigational new drug applications (INDs) or IND amendments or clinical trial authorization applications (CTAs) to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or other regulatory authorities may not permit us to proceed.

Our timing of filing INDs or CTAs on our product candidates is dependent on further research. We cannot be sure that submission of an IND or CTA will result in the FDA or other regulatory authority allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or CTA, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or CTAs.

We have limited experience as a company conducting clinical trials or managing a manufacturing facility for our product candidates.

We have limited experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing clinical trials will be completed on time or if the planned clinical trials will begin or be completed on time, if at all. Large-scale trials would require significant additional

financial and management resources and reliance on third-party clinical investigators, contract research organizations (CROs), or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays that are outside of our control.

In the future, we also intend to operate our own manufacturing facility, which will require significant resources, and we have limited experience as a company in expanding or managing a manufacturing facility. In part because of this lack of experience, we cannot be certain that our manufacturing facility will be completed on time, if at all, or if the planned clinical trials will begin or be completed on time, if at all. In part because of our inexperience, we may have unacceptable or inconsistent product quality success rates and yields, and we may be unable to maintain adequate quality control, quality assurance and qualified personnel. In addition, if we switch from one manufacturing facility to our own manufacturing facility for one or more of our product candidates in the future, we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Failure to successfully create and operate our proposed manufacturing facility could adversely affect the commercial viability of our product candidates.

If serious adverse events or unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit such development.

If our drug candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development, limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective or highlight these risks, side effects, or other characteristics in the approved product label. In pharmaceutical development, many drugs that initially show promise in early-stage testing for treating cancer may later be found to cause side effects that prevent further development of the drug. Currently marketed therapies for the treatment of cancer are generally limited to some extent by their toxicity. In addition, some of our drug candidates would be chronic therapies or be used in pediatric populations, for which safety concerns may be particularly important. Use of our drug candidates as monotherapies may also result in adverse events consistent in nature with other marketed therapies. In addition, if used in combination with other therapies in the future, our drug candidates may exacerbate adverse events associated with the therapy. If serious adverse events or unexpected side effects are identified during development, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) to mitigate those serious safety risks, which could impose significant distribution and/or use restrictions on our products.

The current pandemic of the novel coronavirus, or COVID-19, and the future outbreak of other highly infectious or contagious diseases, could seriously harm our development efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

The extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The rapid development and fluidity of this situation precludes any prediction as to the full adverse impact of the COVID-19 pandemic. Nevertheless, the COVID-19 pandemic may adversely affect our business, financial condition and results of operations, including the below:

- Our operating plan currently includes efforts to advance our PLX9846 product candidate, for the treatment of SM and GIST into further clinical development. We currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our future preclinical and clinical programs and supply other goods and services to run our business. If any such third party in our supply chain for materials is adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery

systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidate for our preclinical program and conduct our research and development operations.

- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur.
- The trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

We may choose not to develop a potential product candidate, or we may suspend, deprioritize or terminate one or more discovery programs or preclinical or clinical product candidates or programs.

At any time and for any reason, we may determine that one or more of our discovery programs or preclinical or clinical product candidates or programs does not have sufficient potential to warrant the allocation of resources toward such program or product candidate. Accordingly, we may choose not to develop a potential product candidate or elect to suspend, deprioritize or terminate one or more of our discovery programs or preclinical or clinical product candidates or programs. If we suspend, deprioritize or terminate a program or product candidate in which we have invested significant resources, we will have expended resources on a program or product candidate that will not provide a full return on our investment and may have missed the opportunity to have allocated those resources to potentially more productive uses, including existing or future programs or product candidates. For example, we concluded enrollment in our ATTCK-20-2 study in the first half of 2019 as a result of emerging clinical data from our Phase 1 ATTCK-20-03 trial, the continuing progress in our ATTCK-20-03 trial, and our desire to efficiently manage resources for our clinical programs. In November 2019, we announced our decision to deprioritize our hematologic programs, to shift our focus to our solid tumor programs and the suspension of further dose escalation in the ATTCK-17-01 trial, pending review of next steps with our collaboration partner, Seattle Genetics. On January 16, 2020, we and Seattle Genetics announced an agreement to terminate the ATTCK-17-01 Phase 1 clinical trial and other research activities under the Collaboration Agreement. In March 2020, we announced the decision to conclude the remaining Phase 1 clinical trials, ATTCK-20-03 and ATTCK-34-01, to focus on development of BOXR1030 and the BOXR platform.

If we fail to develop additional product candidates, our commercial opportunity will be limited.

We are developing a pipeline of product candidates and intend to pursue clinical development of PLX9486 to target SM and GIST and any other product candidates. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds from our initial public offering (IPO) and concurrent private placement with Seattle Genetics, Inc. (Concurrent Private Placement) and issuance of shares in a private placement in 2020 and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA approval to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved product candidate.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. In particular, we may seek to enter into collaborations with our PLX9486 program and other collaborations to progress the clinical development of the PLX9486 program. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- any such collaboration may significantly limit our share of potential future profits from the associated program and may require us to relinquish potentially valuable rights to our current product candidates, potential products, proprietary technologies, or grant licenses on terms that are not favorable to us;
- the collaborations may not result in us achieving revenue to justify such transactions;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the course of development, might cause delays or termination of the development or

commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting, and expensive;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborations may be terminated and upon termination, could result in potential litigation and arbitration proceeding. Further, if we were to incur a loss in the arbitration proceeding, depending on the ruling, we could also be responsible for certain attorney's fees and interest. Given the inherent uncertainty of arbitration and the nature of the potential claim or claims, it is possible that we may incur material losses; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Even if we are successful in entering into a collaboration with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful. As a result, a collaboration may not result in the successful development or commercialization of our product candidates.

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.

The precise incidence and prevalence for GIST and SM are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on estimates, which are inherently uncertain.

The total addressable market opportunity for PLX9486, and any other drug candidates we may produce will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our future approved drugs for sale for these indications, acceptance by the medical community and patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drug, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

The commercial success of any future approved drugs, including PLX9486, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

The commercial success of PLX9486, and of any future approved drugs, will depend in part on market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current cancer treatments, such as surgery, existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If PLX9486 and any future approved drugs do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of PLX9486 and of any current or future drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the availability, perceived advantages, and relative cost, safety, and efficacy of alternative and competing treatments;
- the prevalence and severity of any side effects, adverse reactions, misuse, or any unfavorable publicity in these areas, in particular compared to alternative treatments;

- our ability (and the ability of our licensees) to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength and effectiveness of our marketing, sales, and distribution strategy and efforts, including, without limitation, our own and that of our licensees and distributors, and the degree to which the approved labeling supports promotional initiatives for commercial success;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability and timeliness of third-party payor coverage and adequate reimbursement;
- the inability of patients to afford the out-of-pocket costs of their drug therapy based on their insurance coverage and/or benefit design;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups;
- the labeling of our products, including any significant use or distribution restrictions or safety warnings; and
- any restrictions on the use of our products together with other medications.

Even if a potential drug displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the drug will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our drug may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the therapies marketed by our competitors. Any of these factors may cause PLX9486, or any future approved drugs, to be unsuccessful or less successful than anticipated.

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

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

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

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;

- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- 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.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The development and commercialization of new pharmaceutical and biotechnology products is highly competitive. We face competition with respect to our current clinical-stage drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our drug candidates. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Specifically, there are a large number of pharmaceutical and biotechnology companies developing or marketing treatments for cancer that would be competitive with PLX9486 and the drug candidates we are developing, if such drug candidates are approved. Many of these companies are developing cancer therapeutics that are also kinase inhibitors. Specifically, there are a number of large pharmaceutical companies and biotechnology companies marketing small molecule drugs or biologic drugs for the treatment of GIST, including Blueprint Medicines Corporation (BPMC), Novartis AG (Novartis), Pfizer, Inc. (Pfizer), and Bayer AG. We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST and/or SM including AB Sciences S.A., ARIAD Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, Arog Pharmaceuticals, Inc., AstraZeneca plc, BPMC, Chia Tai Tianqing Pharmaceutical Group CO., LTD, Celldex Therapeutics, Inc., Daiichi Sankyo Company, Limited, Deciphera

Pharmaceuticals, LLC, Exelixis, Inc., Immunicum AB, Jiangsu HengRui, Inc., Ningbo Tai Kang Medical Technology Co. Ltd., Novartis, Taiho Pharmaceutical Co. Ltd, and Xencor, Inc. Some of these competitors are further along in their clinical development programs than we are in ours.

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 side effects, are approved for broader indications or patient populations, are approved for specific sub-populations, are more convenient or are less expensive than PLX9486 or any other products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals, and marketing and selling approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management, and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Our Reliance on Third Parties

We currently rely and for the foreseeable future will continue to rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

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

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

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We contract with third parties for the manufacture of our drug candidates for preclinical development and clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our current and future drugs. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our drug candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or is unable to conduct inspections necessary to approve these facilities due to delays or disruptions caused by the COVID-19 pandemic, or if the FDA or a comparable regulatory authority withdraws any such approval in the future, we may be delayed in obtaining approval of these facilities for the manufacture of our drug candidates or need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our drug candidates.

In response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products while local, national and international conditions warrant. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials which the FDA continues to update. As of June 23, 2020, the FDA noted it was conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain this pace and delays or setbacks are possible in the future. Beginning the week of July 20, 2020, FDA began to work toward resuming prioritized domestic inspections, and as described in an FDA statement on July 10, 2020, the FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

We do not have long-term supply agreements with all of our contract manufacturers, and purchase our required drug supply, including the API, drug product and drug substance used in our drug candidates, on a

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- if the third party ceased its operations for any reason;
- our relative importance as a customer to the third party and whether the third party subordinates our needs to its other customers;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

For our other potential products, if we are not able to negotiate commercial supply terms with any such third-party manufacturers, we may be unable to commercialize our products if they were to be approved, and our business and financial condition would be materially harmed. If we are forced to accept unfavorable terms for our relationships with any such third-party manufacturer, our business and financial condition would be materially harmed.

Third-party manufacturers may not be able to comply with the FDA's cGMP regulations or similar regulatory requirements outside of the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of drug candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Third-party manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, also could result in patient injury or death, product shortages, delays or failures in product testing or delivery, cost overruns, or other problems that could seriously harm our business. Third-party manufacturers often encounter difficulties involving production yields, quality control, and quality assurance, as well as shortages of qualified personnel.

Our drug candidates may compete with other drug candidates for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our drug candidates could result in significant delays or gaps in availability of such drugs or drug candidates and may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

The third parties upon whom we rely for the supply of the API, drug substance and drug product used in PLX9486 are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The API, drug substance and drug product used in PLX9486 are currently supplied to us from single-source suppliers. Our ability to successfully develop our drug candidates, supply our drug candidates for clinical trials and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in

part on our ability to obtain the API, drug substance and drug product for these drugs in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We will need to enter into arrangements to establish redundant or second-source supply of some of the API, drug product or drug substance. If any of our suppliers ceases its operations for any reason or is unable or unwilling to supply API, drug product or drug substance in sufficient quantities or on the timelines necessary to meet our needs, including as a result of the COVID-19 pandemic, it could significantly and adversely affect our business, the supply of our current or future drug candidates or any future approved drugs and our financial condition.

For PLX9486 and any other product candidates, we intend to identify and qualify additional manufacturers to provide such API, drug substance and drug product prior to submission of a New Drug Application (NDA) to the FDA and/or a Marketing Authorization Application (MAA) to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug substance and drug product used in our drug candidates or any future approved drugs, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug substance and drug product used in our current or future drug candidates and any future approved drugs, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug substance and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

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

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

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. Aspects of the ACTR technology are subject to a license from St. Jude Children's Research Hospital (St. Jude's) and the National University of Singapore (NUS). PLX9486 and other molecules are subject to a license from Plexxikon, Inc.

We are currently, and expect in the future to be, party to material license or collaboration agreements. These agreements typically impose numerous obligations, such as diligence and payment obligations. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. These licenses do and future licenses may include provisions that impose obligations and restrictions on us. For example, our license agreement with St. Jude's and NUS imposes some limitations on our ability to assign the license to a party other than an affiliate. This could delay or otherwise negatively impact a transaction that we may wish to enter into.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Currently, we have patents issued from our in-licensed portfolio in AU, EP (validated in DE, FR, and GB), JP, US, SG, and ZA. Except for a ZA patent, no other patents have issued from the patent applications that we own or in-license. We anticipate additional patent applications will be filed both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether any of our intellectual property will provide any competitive advantage;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or

- whether we will need to initiate or defend litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products, such as ACTR-based product candidates, are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We have obtained issuances of composition of matter claims in one European patent from the licensed-in portfolio. We, however, cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered patentable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Various post grant review proceedings, such as inter partes review and post grant review, are available for any interested third party to challenge the patentability of claims issued in patents to us. While these post grant review proceedings have been used less frequently to invalidate biotech patents, they have been successful regarding other technologies, and these relatively new procedures are still changing, and those changes might affect future results.

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when PLX9486 or another product candidate is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to certain intellectual property, through licenses from third parties and under patent applications that we own or will own, related to ACTR087, ACTR707, and PLX9486 constructs, and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights or are pursuing patent rights directed to certain ACTR constructs and PLX9486 we may not be able to obtain intellectual property to broad ACTR constructs and PLX9486 in certain jurisdictions.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antibodies that will be used with our product candidates may be covered by the intellectual property rights of others.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings, including interference proceedings, provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter parties* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and 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 value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might

obtain in the future. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

We have less robust foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

Certain of our key patent families (covering the ACTR087 construct) have been filed in the United States, as well as in numerous jurisdictions outside the United States, and we are pursuing subgeneric claims prior to expiration of applicable deadlines (including a patent family covering the ACTR707 construct). We also plan to pursue claims covering the PLX9486 product in the United States and in jurisdictions outside the United States. However, we have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of the ACTR platform outside of the United States. 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 products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

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 biopharmaceutical 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.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Regulatory Approval of Our Drug Candidates and Other Legal Compliance Matters

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We currently have one drug candidates in clinical development and their risk of failure is high. We are unable to predict when or if any of our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial do not necessarily predict final results. In particular, the small number of patients in our early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. In addition, although we observed encouraging preliminary efficacy results including disease control rates, objective response rates (best response), and progression free survival in our Phase 1 trial of PLX9486, the primary objectives were to determine the safety, tolerability, and maximum tolerated dose of PLX9486 and to determine a recommended Phase 2 dose and not to demonstrate efficacy. The assessments of efficacy from the Phase 1 clinical trial of PLX9486 were not designed to demonstrate statistical significance and may not be predictive of the results of further clinical trials of PLX9486. These factors also apply to any future Phase 1 and Phase 1b/2 trials for other future drug candidates. We did not observe a maximum tolerated dose in the dose escalation stage of our Phase 1 trial of PLX9486.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug candidates, including:

- regulators may not authorize us to commence or continue a clinical trial or may impose a clinical hold or may limit the conduct of a clinical trial through the imposition of a partial clinical hold;
- institutional review boards (IRBs), may not authorize us or our investigators to commence or continue a clinical trial at a prospective trial site or an IRB may not approve a protocol amendment to an ongoing clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials for our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay planned trials, or abandon product development programs;
- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, or the duration of these clinical trials may be longer than we anticipate;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend, change, or terminate clinical trials for our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or IRBs to suspend, change, or terminate the trials;
- unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus, in or around the countries in which we conduct our clinical trials, could delay the commencement or rate of completion of our clinical trials, or those expected to be conducted in China under our collaboration with Zai;

- the cost of clinical trials for our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials for our drug candidates may be insufficient or inadequate and result in delays or suspension of our clinical trials.

While PLX9486 is highly potent and selective KIT D816V inhibitor that is being developed to treat systemic mastocytosis and Gastrointestinal Solid Tumor patients, we may find that patients treated with PLX9486 have or develop mutations that confer resistance to treatment. If patients have or develop resistance to treatment with our drug candidates, we may be unable to successfully complete our clinical trials, and may not be able to obtain regulatory approval of, and commercialize, our drug candidates.

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured, or will be completed on schedule, or at all. We expect presenting additional data from our future clinical trials that may be requested by the FDA. The FDA may request additional information or data and any such requests could result in clinical trial delays. Furthermore, the FDA could place a clinical hold, either another partial clinical hold or a full clinical hold, on our PLX9486 trials if they are not satisfied with the information we provide to them, which could result in delays for the trial. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

We may utilize companion diagnostics in our planned clinical trials in the future in order to identify appropriate patient populations for our drug candidates. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

We plan to advance our lead product candidate, PLX9486, into clinical trials in the future. If we believe the Phase 1 data are compelling, we plan to advance that product candidate in further clinical development for the treatment of GIST patients, we are pursuing development of the compound in patients living with advanced systemic mastocytosis (ASM) and indolent systemic mastocytosis (ISM) to discuss with the FDA the potential to move to a registration trial upon completion of the future clinical trials of that product candidate. However, the general approach for FDA approval of a drug is dispositive data from two adequate and well-controlled, Phase 3 clinical trials of the drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. The FDA may not believe our accelerated approval strategy to move directly to a registration trial upon completion of the current or future Phase 1 clinical trials is warranted and may require a Phase 3 clinical trial or trials prior to approval. Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the number, design, or implementation of our clinical trials, including whether we have identified an appropriate surrogate marker or intermediate clinical endpoint to support an accelerated approval pathway;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

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

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

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

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient

registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Accelerated approval by the FDA, even if granted for PLX9486 or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We plan to seek approval of PLX9486, and may seek approval of future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

If we are unable to successfully develop companion diagnostic tests for our drug candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

We may develop, either by ourselves or with collaborators, in vitro companion diagnostic tests for our drug candidates for certain indications. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory, and logistical challenges. The FDA regulates in vitro companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for our drug candidates, and which will require regulatory clearance or approval prior to commercialization. We may rely on

third parties for the design, development, and manufacture of companion diagnostic tests for our therapeutic drug candidates that require such tests. If these parties are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience delays in doing so, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations, and financial condition could be materially harmed.

The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of any of our drug candidates. Moreover, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests.

In connection with the clinical development of our drug candidates for certain indications, we may work with collaborators to develop or obtain access to in vitro companion diagnostic tests to identify appropriate patients for our drug candidates. We may rely on third parties for the development, testing, and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. Our third-party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our drug candidates. In addition, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required regulatory clearances or approvals and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies.

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

In both domestic and foreign markets, successful sales of our product candidates, if approved, will depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

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

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

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the

resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of a newly approved drug is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act was enacted. The Affordable Care Act, or ACA, and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions will remain in effect through 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. In January 2013, President Obama

signed into law the American Taxpayer Relief Act of 2012 (the ATRA), which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, at the federal level, the U.S. government's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the U.S. government sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously 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. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. On July 24, 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of Health and Human Services to: eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; allow the importation of certain drugs from other countries through individual waivers, permitting the re-importation of insulin products, and prioritizing finalization of the proposed rule to permit the importation of drugs from Canada; depending on whether pharmaceutical manufacturers agree to other measures, ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries; and allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center (FQHC) as part of the 340B drug program to purchase those drugs at the discounted price paid by the FQHC. Because the power to enact policy through Executive Order is limited, these Executive Orders direct HHS to engage the standard rulemaking process. It is not clear when regulators will begin this process and how quickly they will move once they do.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances,

eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the Affordable Care Act. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

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

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our employees, independent contractors, consultants, commercial partners 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 illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, paying, or providing any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to

apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. A person or entity can be found guilty of violating the federal Anti-Kickback Statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or federal civil money penalties statute;

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented; claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false, fictitious or fraudulent claim or obligation to pay or transmit money or property to the federal government; knowingly making or causing a false statement or record to improperly avoid, decrease or conceal an obligation to pay money to the federal government; a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the federal civil False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services (HHS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioner;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients. State laws that may require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources. State and local laws may also require the licensure of sales representatives, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

In 2016, the European Union adopted a new regulation governing the collection, use, storage, disclosure, transfer or processing of personal data, including personal health data practices and privacy called the General Data Protection Regulation (European Union) 2016/679, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company established in the European Economic Area, or EEA (being the European Union plus Norway, Iceland and Liechtenstein) as well as to those outside the EEA if they collect and use personal data in connection with the offering of goods or services to individuals in the European Union or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, expanded disclosures about how personal information is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, mandatory data breach notification requirements, taking certain measures when engaging third-party processors and onerous new obligations on services providers. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR. Non-compliance with the GDPR may result in monetary penalties of up to €20.0 million or 4% of annual worldwide revenue, whichever is higher.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

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

The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure

compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business.

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

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Upon the closing of the IPO, we adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect Unum and its stockholders. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act (referred to as the "TCJA") was enacted in 2017 and significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, a limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses to 80% of current year taxable income and an elimination of net operating loss carrybacks (though any net operating losses generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely), and the modification or repeal of many business deductions and credits.

Additionally, on March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in the combined company's or the combined company's stockholders' tax liability or require changes in the manner in which the combined company operates in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We have not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception (including as a result of the Merger), utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of Unum's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. In addition, our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits.

We face risks arising from the results of the public referendum held in United Kingdom and its membership in the European Union.

The ongoing developments following from the United Kingdom's public referendum vote to exit from the European Union could cause disruptions to and create uncertainty surrounding our business, including affecting

our relationships with existing and potential suppliers, manufacturers, and other third parties. Negotiations have commenced to determine the terms of the United Kingdom's future relationship with the European Union, including the terms of trade between the United Kingdom and the European Union. On January 31, 2020, the United Kingdom formally withdrew from the European Union. A "transition period" will be in effect until the end of December 2020. During this period, most European Union laws will continue to apply. The effects of Brexit will depend upon any agreements the United Kingdom makes to retain access to European Union markets either during this transitional period or more permanently. The measures could potentially have corporate structural consequences, adversely change tax benefits or liabilities in these or other jurisdictions and could disrupt some of the markets and jurisdictions in which we operate. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate. In addition, the announcement of Brexit has caused significant volatility in global stock markets and currency exchange rate fluctuations, including the strengthening of the USD against some foreign currencies, and the Brexit negotiations may continue to cause significant volatility. The progress and outcomes of Brexit negotiations also may create global economic uncertainty. Any of these effects of Brexit, among others, could materially adversely affect the business, business opportunities, and financial condition of our company.

Risks Related to Employee Matters and Managing Growth

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our inability or failure to successfully attract and retain qualified personnel, particularly at the management level, could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer and President, our Chief Financial Officer, and our Chief Medical Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facility in Cambridge, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We maintain a "key man" insurance policy on the life of our Chief Executive Officer and President, but do not maintain "key man" insurance on the lives of our other management personnel or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

We expect to continue to increase our number of employees and expand the scope of our operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Physical expansion of our operations in the future may lead to significant costs, including capital expenditures, and may divert financial resources from other projects, such as the development of our drug candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our 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 drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Interruptions in the availability of server systems or communications with Internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely upon a variety of Internet service providers, third-party hosting facilities and cloud computing platform providers to support our business. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems could damage our reputation in the market, cause us to lose revenue or market share, increase our service costs, cause us to incur substantial costs, subject us to liability for damages and/or fines and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. Any damage to, or failure of, such systems, or communications to and between such systems, could result in interruptions in our operations. If our security measures or those of our third-party data center hosting facilities, cloud computing platform providers, or third-party service partners, are breached, and unauthorized access is obtained to our data or our information technology systems, we may incur significant legal and financial exposure and liabilities.

We do not have control over the operations of the facilities of our cloud service providers and our third party providers may be vulnerable to damage or interruption from natural disasters, cybersecurity attacks,

terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in our cloud service providers' service levels may adversely affect our ability to meet our requirements and operate our business.

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

Our operations, and those of our CROs, CMOs, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, 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 predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

We have broad discretion in the use of working capital and may not use it effectively.

Our management will have broad discretion in the application of working capital, and stockholders do not have the opportunity to assess whether working capital is being used appropriately. Because of the number and variability of factors that will determine our use of our working capital, its ultimate use may vary substantially from its currently intended use. Management might not apply working capital in ways that ultimately increase stockholder value. Failure by us to apply working capital effectively could harm our business. Pending its use, we may invest our working capital in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. In addition, the fair value of such investments is subject to change as a result of potential market fluctuations, including resulting from the impact of the COVID-19 pandemic. If we do not invest or apply our working capital in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Risks Related to Ownership of our Common Stock

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

Our common stock began trading on the Nasdaq Global Select Market on March 29, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares at attractive prices, at the times that they would like to sell them, or at all.

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

The trading price of our common stock is likely to continue to be highly volatile. Market prices for our common stock could be subject to wide fluctuations in response to various factors, including:

- the commencement, enrollment, or results of the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;

- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated

or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed your purchase price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

On December 31, 2019, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market (Nasdaq) notifying us that, for the last 30 consecutive business days, our common stock had not maintained a minimum closing bid price of $1.00 per share (or the Minimum Bid Price Requirement) pursuant to Nasdaq Listing Rule 5450(a)(1). The Nasdaq letter did not result in the immediate delisting of our common stock from The Nasdaq Global Select Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had an initial period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement, which was tolled as of April 16, 2020 and restarted on July 1, 2020. We had until September 11, 2020 to regain compliance with the Minimum Bid Price Requirement. On July 20, 2020, we received notification from the Nasdaq that we had regained compliance with the Minimum Bid Price Requirement.

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

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

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

Our executive officers, directors, and 5% stockholders beneficially owned over 50% of our outstanding common stock as of September 10, 2020. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act) enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the

earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to "opt out" of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance, or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We are a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including "emerging growth companies" such as, but not limited to, potentially not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, 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. Our status as a smaller reporting company is determined on an annual basis. We cannot predict if investors will find our common stock less attractive or our company less comparable to certain other public companies because we will rely on these exemptions. For example, if we do not adopt a new or revised accounting standard, our future financial results may not be as comparable to the financial results of certain other companies in our industry that adopted such standards. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which requires, among other things, that we file with the Securities and Exchange Commission (the SEC), annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and

regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the date of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after other legal restrictions on resale entered into during our IPO, and the Financing and the Merger lapse, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2018 Stock Option and Incentive Plan (2018 Plan) will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the Securities Act). If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of 3,267,483 shares of our common stock as of September 10, 2020, are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2018 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

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

Pursuant to the 2018 Plan, our management is authorized to grant stock options to our employees, directors, and consultants. The number of shares initially reserved for issuance under the 2018 Plan is 2,547,558 plus the 1,030,234 shares of common stock remaining available for issuance under the 2015 Stock Incentive Plan (2015 Plan). Additionally, the shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by us under the 2018 Plan or the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan. As of September 10, 2020, 2,009,911 shares remained available for future issuance under the 2018 Plan. The number of shares of our common stock reserved for issuance under the 2018 Plan shall be cumulatively increased on January 1, 2019 and each January 1 thereafter by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers. In connection with our IPO, we began the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we need as a public company.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

MATERIAL CHANGES

On July 6, 2020, we completed our acquisition of Kiq Bio LLC (formerly Kiq LLC), a Delaware limited liability company ("Kiq"), in accordance with the terms of the Agreement and Plan of Merger, signed and closed on July 6, 2020 (the "Merger Agreement"). Under the terms of the Merger Agreement, at the closing of the Merger, we issued the securityholders of Kiq 6,235,903 shares of the common stock and 44,687 shares of Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"). The Series A Preferred Stock is non-voting and is contingently convertible to common stock subject to stockholder approval. Following stockholder approval, each share of Series A Preferred Stock is convertible into 1,000 shares of common stock at any time at the option of the holder thereof, subject to certain limitations. The estimated consideration for the transaction was approximately $44 million. We concluded to account for this purchase as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, the license rights.

In connection with the Kiq transactions, a non-transferrable contingent value right (a "CVR") was distributed to our stockholders of record as of the close of business on July 6, 2020. Holders of the CVR will be entitled to receive certain stock and/or cash payments from proceeds received us, if any, related to the disposition of its legacy cell therapy assets for a period of three years following the closing of the transaction.

We have agreed to hold a stockholders' meeting to submit the approval of the conversion of the Series A Preferred Stock into shares of common stock, the approval of an amendment to our certificate of incorporation to authorize sufficient shares of common stock for the conversion of the Series A Preferred Stock issued and the approval of a reverse stock split of all outstanding shares of common stock for the purpose of maintaining compliance with Nasdaq listing standards.

In connection with the Kiq merger, on July 9, 2020, we also completed a private placement of 118,638 Series A Preferred Stock to new and existing investors in exchange gross proceeds of $104.4 million.

On August 28, 2020, we entered into an asset purchase agreement with Sotio, pursuant to which, among other things, Sotio agreed to acquire from us assets relating to our Bolt-On Chimeric Receptor ("BOXR") technology and Autologous Cell Therapy Industrial Automation ("ACTIA") technology (collectively, the "BOXR Platform"), for total cash consideration of up to $11.5 million, consisting of an upfront payment of $8.1 million ($1.725 million of which was placed in escrow for 90 days) and potential milestone payments of up to $3.4 million in the aggregate upon the achievement of certain milestones.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the Shares in this offering. The Selling Shareholders will receive all of the proceeds from this offering.

SELLING SHAREHOLDERS

This prospectus covers the resale or other disposition from time to time by the Selling Shareholders identified in the table below of up to an aggregate of 169,530,903 of our Shares.

On July 6, 2020, we entered into a securities purchase agreement with the Selling Shareholders, or the Securities Purchase Agreement, pursuant to which we sold an aggregate of 118,638 shares of our Series A Non-Voting Convertible Preferred Stock, par value $0.001 per share, or the Series A Preferred Stock, at an aggregate purchase price of approximately $104.4 million. Also on July 6, 2020, we completed our acquisition of Kiq Bio LLC in accordance with the Merger Agreement, pursuant to which we issued an aggregate of 6,235,903 shares of our Common Stock, par value $0.001 per share and 44,687 shares of our Series A Preferred Stock to certain of the Selling Shareholders. This prospectus covers the resale or other disposition by the Selling Shareholders or their transferees of up to the total number of shares issued to the Selling Shareholders pursuant to the Merger Agreement or issuable upon the conversion of the Series A Non-Voting Convertible Preferred Shares sold pursuant to the Securities Purchase Agreement or the Merger Agreement. Throughout this prospectus, when we refer to the Selling Shareholders, we are referring to the purchasers under the Securities Purchase Agreement or certain of the securityholders under the Merger Agreement.

We are registering the above-referenced Shares to permit the Selling Shareholders and their pledgees, donees, transferees or other successors-in interest that receive their shares after the date of this prospectus to resell or otherwise dispose of the shares in the manner contemplated under “Plan of Distribution” herein.

Except as otherwise disclosed herein, the Selling Shareholders do not have, and within the past three years have not had, any position, office or other material relationship with us.

The following table sets forth the name of the Selling Shareholders, the number of shares owned by the Selling Shareholders, the number of shares that may be offered under this prospectus and the number of our shares that will be owned by the Selling Shareholders assuming all of the Shares registered for resale hereby are sold. The number of shares set forth below assumes the conversion of one share of Series A Preferred Stock to 1,000 shares of Common Stock.

The Selling Shareholders may sell some, all or none of their shares. We do not know how long the Selling Shareholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the Selling Shareholders regarding the sale or other disposition of any of the Shares. The Shares covered hereby may be offered from time to time by the Selling Shareholders, provided that Shares issued upon conversion of Series A Preferred Stock may only be offered after the Shares are converted to Common Stock pursuant to the terms of a certificate of designation of preferences, right and limitations of Series A Non-Voting Convertible Preferred Stock and only upon approval by our stockholders of a stock split of all outstanding shares of Common Stock.

The information set forth below is based upon information obtained from the Selling Shareholders and upon information in our possession regarding the issuance of the Shares in connection with the 2020 Private Placement and the Merger. The percentage of ordinary shares owned after the offering are based on 42,469,409 shares of common stock outstanding as of September 10, 2020, and, for each Selling Shareholder, assume the conversion of only the Series A Preferred Stock owned by such Selling Shareholder but not the Series A Preferred Stock owned by any other Selling Shareholder.

Name of Selling Shareholders	Common Stock Beneficially Owned before Offering (1)	Common Stock that may be Offered Pursuant to Prospectus	Common Stock Beneficially Owned After Offering (1)	
			Number	Percentage (%)
Entities associated with Fairmount (2)	73,619,903	73,619,903	0	*
Entities associated with Venrock (3)	17,991,273	13,636,000	4,355,273	7.8%
Acorn Bioventures, L.P	11,364,000	11,364,000	0	*
Entities associated with Atlas (4)	14,725,535	11,364,000	3,361,535	6.2%
Entities associated with Biotechnology Value (5)	11,364,000	11,364,000	0	*
Perceptive Life Sciences Master Fund, Ltd.	7,955,000	7,955,000	0	*
Entities associated with RTW (6)	7,955,000	7,955,000	0	*
Entities associated with OrbiMed (7)	7,955,000	7,955,000	0	*
Ally Bridge MedAlpha Master Fund L.P.	5,682,000	5,682,000	0	*
Logos Opportunities Fund II, L.P.	5,682,000	5,682,000	0	*
Samsara BioCapital, L.P (8)	5,682,000	5,682,000	0	*
Ridgeback Capital Investments LP (9)	5,809,000	3,409,000	2,400,000	5.2%
Commodore Capital Master LP	2,557,000	2,557,000	0	*
Wedbush Healthcare Partners 2020 Fund, LLC	1,136,000	1,136,000	0	*
Dellora Investments Fund LP	170,000	170,000	0	*

* Less than 1%

(1) "Beneficial ownership" is a term broadly defined by the SEC in Rule 13d-3 under the Exchange Act, and includes more than the typical form of stock ownership, that is, stock held in the person's name. The term also includes what is referred to as "indirect ownership," meaning ownership of shares as to which a person has or shares investment power.

(2) Consists of (i) 55,470,000 common stock issuable upon the conversion of Series A Preferred Stock held by Fairmount Healthcare Fund II LP, (ii) 5,088,497 common stock shares held by Fairmount Healthcare Fund II LP, (iii) 11,914,000 common stock issuable upon the conversion of Series A Preferred Stock held by Fairmount Healthcare Fund LP, and (iv) 1,147,406 common stock shares held by Fairmount Healthcare Fund LP. Fairmount Healthcare Fund GP LLC is the general partner of Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II GP LLC is the general partner of Fairmount Healthcare Fund II LP. Fairmount Funds Management LLC is the investment manager of Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II LP. Fairmount Funds Management LLC, as the investment manager, along with Fairmount Healthcare Fund GP LLC and Fairmount Healthcare Fund II GP LLC, as the general partners, exercise voting and investment power over Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II LP. Tomas Kiselak and Peter Harwin are the voting members of Fairmount Funds Management LLC, Fairmount Healthcare Fund GP LLC and Fairmount Healthcare Fund II GP LLC. The address for the beneficial owners is 2001 Market Street Suite 2500 Philadelphia PA 19103.

(3) Includes (i) 2,489,042 shares of common stock held by Venrock Healthcare Capital Partners III, L.P., (ii) 1,151,100 shares of common stock held by Venrock Healthcare Capital Partners II, L.P., (iii) 248,686 shares of common stock held by VHCP Co-Investment Holdings III, LLC and (iv) 466,445 shares of common stock held by VHCP Co-Investment Holdings II, LLC. Also includes (i) 7,793,000 shares of common stock issuable upon conversion of Series A Preferred Stock held by Venrock Healthcare Capital Partners III, L.P., (ii) 3,604,000 shares of common stock issuable upon conversion of Series A Preferred Stock held by Venrock Healthcare Capital Partners II, L.P., (iii) 779,000 shares of common stock issuable upon conversion of Series A Preferred Stock held by VHCP Co-Investment Holdings III, LLC and (iv) 1,460,000 shares of common stock issuable upon conversion of Series A Preferred Stock held by VHCP Co-Investment Holdings II, LLC, which, in each case, are subject to a limitation on conversion to common stock under the terms of the Company's Certificate of Designations to the extent that, following conversion thereof, these entities would beneficially own in excess of 9.9% of the Company's common stock. VHCP Management II, LLC is the general partner of Venrock Healthcare Capital Partners II, L.P. and the manager of VHCP Co-Investment Holdings II, LLC. VHCP

Management III, LLC is the general partner of Venrock Healthcare Capital Partners III, L.P. and the manager of VHCP Co-Investment Holdings III, LLC. Messrs. Nimish Shah and Bong Koh are the voting members of VHCP Management II, LLC and VHCP Management III, LLC .The address for the beneficial owners is 3340 Hillview Avenue, Palo Alto, California 94304.

(4) Consists of (i) 11,364,000 common stock issuable upon conversion of Series A Preferred Stock held by Atlas Venture Fund XI, L.P. ("Atlas Venture Fund XI") and (ii) 3,361,535 shares of common stock held by Atlas Venture Fund IX, L.P. ("Atlas Venture Fund IX"). The general partner of Atlas Venture Fund XI is Atlas Venture Associates XI, L.P. ("AVA XI LP"). Atlas Venture Associates XI, LLC ("AVA XI LLC") is the general partner of AVA XI LP. Each of AVA XI LP and AVA XI LLC disclaims Section 16 beneficial ownership of the securities held by Atlas Venture Fund XI, except to the extent of its pecuniary interest therein, if any. The general partner of Atlas Venture Fund IX is Atlas Venture Associates IX, L.P. ("AVA IX LP"). Atlas Venture Associates IX, LLC ("AVA IX LLC") is the general partner of AVA IX LP. Each of AVA IX LP and AVA IX LLC disclaims Section 16 beneficial ownership of the securities held by Atlas Venture Fund IX, except to the extent of its pecuniary interest therein, if any. The address of Atlas Venture Fund IX, L.P., AVA IX LP, and AVA IX LLC is 46 Wareham Street, Boston, MA 02118.

(5) Consists of (i) 772,000 common stock issuable upon the conversion of Series A Preferred Stock held by Biotechnology Value Trading Fund OS, L.P ("Trading Fund OS"); (ii) 4,427,000 common stock issuable upon the conversion of Series A Preferred Stock held by Biotechnology Value Fund II, L.P. ("BVFII") (iii) 5,936,000 common stock issuable upon the conversion of Series A Preferred Stock held by Biotechnology Value Fund, L.P. ("BVF"), and (iv) 229,000 common stock issuable upon the conversion of Series A Preferred Stock held by MSI BVF SPV L.L.C ("MSI"). The number of shares of common stock into which the Series A Preferred Stock are convertible is limited to that number of shares of common stock which would result in the stockholders, together with its affiliates, having an aggregate beneficial ownership of no more than 9.99% of the total issued and outstanding shares of common stock. BVF I GP, as the general partner of BVF, may be deemed to beneficially own the securities owned by BVF. BVF II GP, as the general partner of BVF, may be deemed to beneficially own the securities owned by BVFII. BVF GP Holdings LLC, as the sole member of BVF I GP and BVF II GP, may be deemed to beneficially own securities owned directly by BVF and BVFII. BVF Partners OS Ltd. ("Partners OS"), as the general partner of Trading Fund OS, may be deemed to beneficially own the securities owned by Trading Fund OS. BVF Partners, as the investment manager of BVF, BVFII, Trading Fund OS and MSI, may be deemed to beneficially own the shares owned by BVF, BVFII, Trading Fund OS and MSI. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the shares beneficially owned by BVF Partners. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the shares beneficially owned by BVF Inc. The address of the beneficial owners is 44 Montgomery St., 40th Floor, San Francisco, California 94104.

(6) Consists of 7,955,000 common stock issuable upon the conversion of Series A Preferred Stock held in the aggregate by RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd. and RTW Venture Fund Limited (the "RTW Funds"). The Funds are managed by RTW Investments, LP ("RTW"). RTW, in its capacity as the investment manager of the Funds, has the power to vote and the power to direct the disposition of the shares held by the RTW Funds. Accordingly, RTW may be deemed to be the beneficial owner of such securities. Roderick Wong, M.D., as the Managing Partner of RTW, has the power to direct the vote and disposition of the securities held by RTW. Dr. Wong disclaims beneficial ownership of the shares held by the RTW Funds, except to the extent of his pecuniary interest therein. The address and principal office of RTW Investments, LP is 40 10th Avenue, Floor 7, New York, NY 10014, and the address of Dr. Wong and each of the RTW Funds is c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014.

(7) Consists of (i) 2,273,000 common stock issuable upon the conversion of Series A Preferred Stock held by OrbiMed Genesis Master Fund, L.P. and (ii) 5,682,000 common stock issuable upon the conversion of Series A Preferred Stock held by OrbiMed Partners Master Fund Limited. OrbiMed Genesis GP LLC is the general partner of OrbiMed Genesis Master Fund, L.P. and OrbiMed Advisors LLC is the managing member of OrbiMed Genesis GP LLC. By virtue of such relationships, OrbiMed Genesis GP LLC and OrbiMed Advisors LLC may be deemed to have voting power and investment power over the securities held by OrbiMed Genesis Master Fund, L.P. and as a result, may be deemed to have beneficial ownership over

such securities. OrbiMed Capital LLC is the investment advisor to OrbiMed Partners Master Fund Limited. OrbiMed Advisors LLC and OrbiMed Capital LLC exercise voting and investment power through a management committee comprised of the Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OrbiMed Genesis Master Fund, L.P. and OrbiMed Partners Master Fund Limited. The address for the OrbiMed Entities is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(8) Consists of 5,682,000 common stock issuable upon the conversion of Series A Preferred Stock held directly by Samsara BioCapital, L.P., a Delaware limited partnership with a business address of 628 Middlefield Road, Palo Alto, CA 94301. Dr. Srinivas Akkaraju, MD, PhD, is the managing member of Samsara BioCapital GP, LLC, the general Partner of Samsara BioCapital, L.P. Dr. Akkaraju disclaims beneficial ownership of these securities except to the extent of this pecuniary interest therein.

(9) Consists of (i) 2,400,000 shares of common stock held by Ridgeback Capital Investments LP ("RCILP") and (ii) 3,409,000 shares of common stock issuable upon the conversion of the Series A Preferred Stock held by Ridgeback Capital Management LLC ("RCM"). The shares of common stock issuable upon conversion of the Series A Preferred Stock owned by RCM will be issued to RCILP, subject to a 9.99% limitation. Ridgeback Capital Investments Ltd. ("RCI") is the general partner of RCILP. Pursuant to an investment management agreement, RCM maintains investment and voting power with respect to the securities held or controlled by RCI. Wayne Holman, an individual, controls RCM. The address for the Ridgeback entities is 348 West 14th Street, New York, NY 10014.

Relationship with the Selling Shareholders

In addition to the Securities Purchase Agreement, on July 6, 2020, in connection with the 2020 Private Placement, we entered into a registration rights agreement with the Selling Shareholders, or the Registration Rights Agreement.

Registration Rights Agreement

Pursuant to the Registration Rights Agreement with the Selling Shareholders, we agreed to prepare and file with the SEC a registration statement that permits the resale or other disposition of the Selling Shareholders' Shares issued upon conversion of the Series A Preferred Stock issued to such Selling Shareholder pursuant to the Securities Purchase Agreement and, subject to certain exceptions, use commercially reasonable efforts to keep the registration statement of which this prospectus forms a part effective under the Securities Act for so long as such securities registered for resale thereunder retain their character as Registrable Securities.

We have also agreed, among other things, to indemnify the Selling Shareholders and their officers, directors, agents, partners, members, managers, stockholders, affiliates and employees from certain liabilities and to pay all fees and expenses incident to our obligations under the Registration Rights Agreement.

PLAN OF DISTRIBUTION

We are registering the Shares issued to the selling stockholders to permit the resale of these Shares by the holders of the Shares from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the Shares. We will, or will procure to, bear all fees and expenses incident to our obligation to register the Shares.

The selling stockholders may sell all or a portion of the Shares beneficially owned by them and offered hereby from time to time, and in the case of Shares issued upon conversion of Series A Preferred Stock, may only be offered after the Shares are converted to Common Stock pursuant to the terms of a certificate of designation of preferences, right and limitations of Series A Non-Voting Convertible Preferred Stock and only upon approval by our stockholders of a stock split of all outstanding shares of Common Stock, directly or through one or more underwriters, broker-dealers or agents. If the Shares are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The Shares may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as amended, or the Securities Act, as permitted by that rule, or Section 4(a)(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

Broker dealers engaged by the selling stockholders may arrange for other broker dealers to participate in sales. If the selling stockholders effect such transactions by selling Shares to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the Shares for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2121.01.

In connection with sales of the Shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the Shares in the course of hedging in positions they assume. The selling stockholders may also sell Shares short and if such short sale shall take place after the date that this Registration Statement is declared effective by the Commission, the selling stockholders may deliver Shares covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge Shares to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered on this registration statement to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Shares from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the Shares in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer or agents participating in the distribution of the Shares may be deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling Stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the applicable prospectus delivery requirements of the Securities Act including Rule 172 thereunder and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Each selling stockholder has informed the Company that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the Shares. Upon the Company being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of Common Stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the Shares were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent (8.0%).

Under the securities laws of some U.S. states, the Shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some U.S. states the Shares may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the Shares registered pursuant to the shelf registration statement, of which this prospectus forms a part.

Each selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the Shares by the selling stockholder and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the Shares to engage in market-making activities with respect to the Shares. All of the foregoing may affect the marketability of the Shares and the ability of any person or entity to engage in market-making activities with respect to the Shares.

We will pay all expenses of the registration of the Shares pursuant to the registration rights agreement, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that each selling stockholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it. We will indemnify the selling stockholders against certain liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreement, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, in accordance with the related registration rights agreements, or we may be entitled to contribution.

DESCRIPTION OF CAPITAL STOCK

The following summary of the general terms and provisions of the registered capital stock of Unum does not purport to be complete and is subject to, and qualified in its entirety by, reference to our Amended and Restated Certificate of Incorporation ("certificate of incorporation"), including the Certificate of Designations of Preferences, Right and Limitations of Series A Non-Voting Convertible Preferred Stock (the "Certificate of Designation"), and our Amended and Restated Bylaws ("bylaws") each of which is incorporated by reference herein, and applicable provisions of the Delaware General Corporation Law ("DGCL"). Our common stock, par value $0.001 per share is registered pursuant to Section 12(b) of the Securities and Exchange Act of 1934 and trades on the Nasdaq Global Select Market under the symbol UMRX. The summaries below do not purport to be complete statements of the relevant provisions of the certificate of incorporation, the bylaws or the DGCL.

General

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share, 1,000,000 of which are designated as Series A Non-Voting Convertible Preferred Stock and 9,000,000 of which shares of preferred stock are undesignated.

Pursuant to the Merger Agreement, we agreed to hold a stockholders' meeting to submit the following matters to our stockholders for their consideration: (i) the approval of the conversion of the Series A Non-Voting Convertible Preferred Stock into shares of common stock in accordance with Nasdaq Listing Rule 5635(a) ("Conversion Proposal"), (ii) the approval of an amendment to our certificate of incorporation to authorize sufficient shares of common stock for the conversion of the Series A Non-Voting Convertible Preferred Stock issued pursuant to the Merger Agreement and the Securities Purchase Agreement (the "Charter Amendment Proposal") and (iii) the approval of a reverse stock split of all outstanding shares of common stock for the purpose of maintaining compliance with Nasdaq listing standards, if deemed necessary by us. Unum and Kiq no longer believe it is necessary to submit the Charter Amendment Proposal to our stockholders for their consideration.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution, or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Exchange Listing

Our common stock is listed on The Nasdaq Global Select Market under the symbol "UMRX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

Series A Non-Voting Convertible Preferred Stock

Holders of Series A Non-Voting Convertible Preferred Stock are entitled to receive dividends on shares of Series A Non-Voting Convertible Preferred Stock equal to, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the Series A Non-Voting Convertible Preferred Stock does not have voting rights. However, as long as any shares of Series A Non-Voting Convertible Preferred Stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Non-Voting Convertible Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Non-Voting Convertible Preferred Stock, (b) alter or amend the Certificate of Designation, (c) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Non-Voting Convertible Preferred Stock, (d) increase the number of authorized shares of Series A Non-Voting Convertible Preferred Stock, (e) prior to the stockholder approval of the Conversion Proposal or at any time while at least 40% of the originally issued Series A Non-Voting Convertible Preferred Stock remains issued and outstanding, consummate a Fundamental Transaction (as defined in the Certificate of Designation) or (f) enter into any agreement with respect to any of the foregoing. The Series A Non-Voting Convertible Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

Following stockholder approval of the Conversion Proposal, each share of Series A Non-Voting Convertible Preferred Stock is convertible into 1,000 shares of common stock at any time at the option of the holder thereof, subject to certain limitations, including that a holder of Series A Non-Voting Convertible Preferred Stock is prohibited from converting shares of Series A Non-Voting Convertible Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be established by the holder between 4.9% and 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 9,000,000 additional shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of additional shares of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of additional shares of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. 163,295 shares of Series A Non-Voting Convertible Preferred Stock are outstanding. We have no present plan to issue any additional shares of preferred stock.

Registration Rights

Certain of the holders of our Series A Non-Voting Convertible Preferred Stock are entitled to certain rights with respect to the registration of such securities as further provided under the heading “Selling Shareholders – Registration Rights Agreement”.

Certain of the holders of our common stock are entitled to rights with respect to the registration of such securities as set forth below under the Securities Act. These rights are provided under the terms of an amended and restated investors’ rights agreement between us and certain holders our common stock. The amended and restated investors’ rights agreement includes demand registration rights, short-form registration rights, and piggyback registration rights. All fees, costs and expenses of underwritten registrations under these agreements will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be

borne by the holders of the shares being registered. The holders of two-thirds of the registrable securities, as such term is defined in the amended and restated investors' rights agreement, have waived all applicable registration rights in connection with this offering.

Demand Registration Rights

Under the terms of the amended and restated investors' rights agreement, we will be required, upon the written request of holders of at least 30% of these securities, to file a registration statement and use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the investor rights agreement.

Short-Form Registration Rights

Under the terms of the amended and restated investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of 15% in interest of these holders to sell registrable securities at an anticipated aggregate price of at least $5 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only two registrations in any 12-month period pursuant to this provision of the amended and restated investors' rights agreement.

"Piggyback" Registration Rights

If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the amended and restated investors' rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our amended and restated investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expenses of Registration

We are generally required to bear all registration and selling expenses incurred in connection with the demand, short-form and piggyback registration described above, other than underwriting discounts and selling commissions.

Expiration of Registration Rights

The demand registration rights and short form registration rights granted under the amended and restated investors' rights agreement will terminate as to a given holder of registrable securities on the earliest to occur of (i) the fifth anniversary of the completion of our IPO, (ii) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares without limitation during a three-month period without registration and (iii) the closing of a deemed liquidation event, as such term is defined in our certificate of incorporation.

Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Certain provisions of the Delaware General Corporation Law and of our amended and restated certificate of incorporation and amended and restated by-laws could have the effect of delaying, deferring or discouraging

another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66.67% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairperson of the board, our chief executive officer, or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exists any vacancies); and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against the us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences, and privileges thereto, would require the affirmative vote of the holders of at least 66.67% of the voting power of all of our then outstanding common stock.

LEGAL MATTERS

Certain legal matters with respect to United States law in connection with this offering will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2019 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement that we have filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules of the SEC. For further information, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Statements contained in this prospectus or incorporated by reference concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed or incorporated by reference as an exhibit to the registration statement, we refer you to the copy of the contract or document that has been filed. Each statement in this prospectus or incorporated by reference relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains a web site *(http://www.sec.gov)* that contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC.

We are subject to the reporting and information requirements of the Exchange Act and, as a result, we file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection on the web site of the SEC referred to above.

INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference the information and reports we file with it, which means that we can disclose important information to you by referring you to these documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede the information already incorporated by reference. We are incorporating by reference the documents listed below, which we have already filed with the SEC, and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including all filings made after the date of the filing of this registration statement and prior to the effectiveness of this registration statement, except as to any portion of any future report or document that is not deemed filed under such provisions, after the date of this prospectus and prior to the termination of this offering:

- Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 26, 2020;
- Quarterly Reports on Form 10-Q, as filed with the SEC on May 11, 2020 and August 11, 2020;
- The information specifically incorporated by reference in our Annual Report on Form 10-K for the year ended December 31, 2019, from our Definitive Proxy Statement on Schedule 14(a), as filed with the SEC on April 29, 2020;
- Current Reports on Form 8-K (other than information furnished rather than filed) filed with the SEC on January 6, 2020, January 13, 2020, January 17, 2020, January 29, 2020, March 2, 2020, March 9, 2020, March 10, 2020, March 16, 2020, March 20, 2020, May 11, 2020, May 15, 2020, June 10, 2020, July 6, 2020, August 10, 2020, and September 3, 2020; and
- The description of our common stock contained in exhibit 4.3 to our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 26, 2020, including any amendments or reports filed for the purposes of updating this description.

Notwithstanding the foregoing, unless specifically stated to the contrary, information that we furnish (and that is not deemed "filed" with the SEC) under Items 2.02 and 7.01 of any Current Report on Form 8-K, including the related exhibits under Item 9.01, is not incorporated by reference into this prospectus or the registration statement of which this prospectus is a part.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Unum Therapeutics Inc., 200 CambridgePark Drive, Suite 3100, Cambridge, Massachusetts 02140, telephone: (617) 945-5576.

You also may access these filings on our website at *www.unumrx.com* . We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

169,530,903 Shares

Common Stock

Offered by the Selling Shareholders

PROSPECTUS

, 2020

Part II—INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The expenses payable by us in connection with the issuance and distribution of the securities being registered (other than underwriting discounts and commissions, if any) are set forth below. Each item listed is estimated, except for the SEC registration fee.

Securities and Exchange Commission registration fee	$ 64,144.90
Legal fees and expenses	*
Accounting fees and expenses	*
Printing fees and expenses	*
Transfer agent and trustee fees	*
Miscellaneous	*
Total	$ *

* Estimated expenses not presently known. Each prospectus supplement will reflect estimated expenses based on the amount of the related offering.

Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law (DGCL) authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines, and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

Provisions in our certificate of incorporation and amended and restated bylaws limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies, such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Item 16. Exhibits

A list of exhibits filed with this registration statement on Form S-3 is set forth on the Exhibit Index and is incorporated herein by reference.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(a)(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended ("Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the

Securities Exchange Act of 1934, as amended ("Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date;

(b) That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

EXHIBIT INDEX

Exhibit No.	Description
3.1*	Form of Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-223414) filed March 19, 2018)
3.2*	Amendment to the Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K, filed on July 6, 2020)
3.3*	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of Unum Therapeutics Inc., dated July 6, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on July 6, 2020)
4.1*	Securities Purchase Agreement, dated July 6, 2020, by and among Unum Therapeutics Inc. and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K, filed on July 6, 2020)
4.2*	Registration Rights Agreement, dated July 6, 2020, by and among Unum Therapeutics Inc. and the Purchasers named therein (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K, filed on July 6, 2020)
5.1	Opinion of Goodwin Procter LLP
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.2	Consent of Goodwin Procter LLP (included in Exhibit 5.1 hereto)
24.1	Power of Attorney (included on the signature pages to the registration statement)

* Previously filed.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, State of Massachusetts, on the 22nd day of September, 2020.

UNUM THERAPEUTICS INC.

By: /s/ Charles Wilson
Charles Wilson, Ph.D.
Chief Executive Officer and President

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Charles Wilson, Ph.D. and John Green and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney in fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Registration Statement, including any and all post effective amendments and amendments thereto, and any registration statement relating to the same offering as this Registration Statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys in fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys in fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following person in the capacities and on the date indicated.

Name	Title	Date
/s/ Charles Wilson Charles Wilson, Ph.D.	Chief Executive Officer, President and Director (*Principal Executive Officer*)	September 22, 2020
/s/ John Green John Green	Chief Financial Officer (*Principal Financial and Accounting Officer*)	September 22, 2020
/s/ Chris Cain Chris Cain, Ph.D.	Director	September 22, 2020
/s/ Peter Harwin Peter Harwin	Director	September 22, 2020
/s/ Karen Ferrante, M.D. Karen Ferrante, M.D.	Director	September 22, 2020
/s/ Matthew Ros Matthew Ros	Director	September 22, 2020
/s/ Arlene Morris Arlene Morris	Director	September 22, 2020

Exhibit 5.1

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210

goodwinlaw.com
+1 617 570 1000

September 22, 2020

Unum Therapeutics Inc.
200 Cambridge Park Drive, Suite 2500
Cambridge, MA 02140

Re: Securities Registered under Registration Statement on Form S-3

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-3 (as amended or supplemented, the "Registration Statement") filed on September 22, 2020 with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of up to (i) 6,235,903 shares (the "Common Shares") of the common stock, par value $0.001 per share (the "Common Stock"), of Unum Therapeutics Inc., a Delaware corporation (the "Company") and (ii) 163,295,000 shares (the "Series A Conversion Shares", and together with the Common Shares, the "Shares") of Common Stock issuable upon conversion of the Company's Series A Non-Voting Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock") to be sold by the selling shareholders listed in the Registration Statement under "Selling Shareholders" (the "Selling Shareholders").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers of the Company. For purposes of the opinion set forth below, we have assumed that before the Shares are issued the Company does not issue shares of Common Stock or reduce the total number of shares of Common Stock that the Company is authorized to issue under its certificate of incorporation such that the number of unissued shares of Common Stock authorized under the Company's certificate of incorporation is less than the number of Shares.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that the Shares have been duly authorized and validly issued and are fully paid and nonassessable.

The opinion set forth above is subject to the following qualifications:

(a) that before the Series A Conversion Shares are issued, the Company's shareholders shall approve the conversion of the Series A Preferred Stock into shares of Common Stock; and

(b) that before the Series A Conversion Shares are issued, the Company's shareholders shall approve, and the Company shall effect, a reverse stock split of the Company's Common Stock.

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Goodwin Procter LLP

GOODWIN PROCTER LLP

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of Unum Therapeutics Inc. of our report dated March 26, 2020 relating to the financial statements, which appears in Unum Therapeutics Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
September 22, 2020