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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2021**

**OR**

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

**For the transition period from _____ to _____.**

**Commission File Number: 001-40800**

# TYRA BIOSCIENCES, INC.

**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **83-1476348** |
|---|---|
| **( State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **2656 State Street Carlsbad, California** | **92008** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (619) 728-4760**

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

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

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

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

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

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

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

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

As of October 31, 2021, the registrant had 41,265,756 shares of common stock, $0.0001 par value per share, outstanding.

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**PART I—FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Tyra Biosciences, Inc.**
**Balance Sheets**
(in thousands, except share and par value data)

| | September 30, 2021 (unaudited) | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 312,823 | $ 15,224 |
| Prepaid and other current assets | 678 | 57 |
| Total current assets | 313,501 | 15,281 |
| Restricted cash | 243 | 243 |
| Property and equipment, net | 779 | 297 |
| Right-of-use asset | 1,129 | 169 |
| Other long-term assets | 318 | 21 |
| Total assets | $ 315,970 | $ 16,011 |
| **Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable (including related party amounts of $68 and $0, respectively) | $ 2,068 | $ 664 |
| Lease liabilities, current | 135 | 142 |
| Accrued and other current liabilities | 2,565 | 1,052 |
| Total current liabilities | 4,768 | 1,858 |
| Lease liabilities, noncurrent | 1,037 | — |
| Other long-term liabilities | 434 | 140 |
| Total liabilities | 6,239 | 1,998 |
| Commitments and contingencies (Note 2) | | |
| Convertible preferred stock, $0.0001 par value; no shares and 6,223,046 shares authorized at September 30, 2021 and December 31, 2020, respectively; no shares and 3,374,560 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively | — | 27,651 |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.0001 par value; 50,000,000 shares and no shares authorized at September 30, 2021 and December 31, 2020, respectively; no shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively | — | — |
| Common stock, $0.0001 par value; 500,000,000 and 50,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 42,535,661 and 3,050,781 shares issued at September 30, 2021 and December 31, 2020, respectively, and 41,207,660 and 1,829,377 shares outstanding at September 30, 2021 and December 31, 2020, respectively | 4 | — |
| Additional paid-in capital | 340,168 | 439 |
| Accumulated deficit | (30,441) | (14,077) |
| Total stockholders' equity (deficit) | 309,731 | (13,638) |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) | $ 315,970 | $ 16,011 |

*See accompanying notes to unaudited financial statements.*

**Tyra Biosciences, Inc.**
**Statements of Operations and Comprehensive Loss**
(unaudited)
(in thousands, except share and per share data)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development | $ 5,484 | $ 1,862 | $ 13,386 | $ 4,275 |
| General and administrative (including related party amounts of $142, $0, $260 and $0, respectively) | 1,154 | 470 | 2,970 | 1,345 |
| Total operating expenses | 6,638 | 2,332 | 16,356 | 5,620 |
| Loss from operations | (6,638) | (2,332) | (16,356) | (5,620) |
| Other (expense) income: | | | | |
| Interest income | 2 | — | 8 | 1 |
| Change in fair value of simple agreement for future equity | — | — | — | (15) |
| Other expense | (7) | (7) | (16) | (17) |
| Total other expense | (5) | (7) | (8) | (31) |
| Net loss and comprehensive loss | $ (6,643) | $ (2,339) | $ (16,364) | $ (5,651) |
| Net loss per share, basic and diluted | $ (0.72) | $ (1.47) | $ (3.63) | $ (3.83) |
| Weighted-average shares used to compute net loss per share, basic and diluted | 9,164,003 | 1,594,873 | 4,504,997 | 1,475,266 |

*See accompanying notes to unaudited financial statements.*

**Tyra Biosciences, Inc.**
**Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**
(unaudited)
(in thousands, except share amounts)

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| **Balance at December 31, 2019** | — | $ — | — | $ — | 2,705,779 | $ — | $ — | $ (4,741) | $ (4,741) |
| Issuance of Series A convertible preferred stock upon conversion of simple agreement for future equity | 526,074 | 4,340 | — | — | — | — | — | — | — |
| Issuance of Series A convertible preferred stock, net of issuance costs | 2,848,486 | 23,311 | — | — | — | — | — | — | — |
| Incremental vesting conditions placed on previously issued common shares | — | — | — | — | (1,461,816) | — | — | — | — |
| Vesting of shares of common stock subject to repurchase | — | — | — | — | 147,172 | — | — | — | — |
| Stock-based compensation | — | — | — | — | — | — | 108 | — | 108 |
| Net loss | — | — | — | — | — | — | — | (1,474) | (1,474) |
| **Balance at March 31, 2020** | 3,374,560 | $ 27,651 | — | $ — | 1,391,135 | $ — | $ 108 | $ (6,215) | $ (6,107) |
| Vesting of shares of common stock subject to repurchase | — | — | — | — | 147,172 | — | — | — | — |
| Stock-based compensation | — | — | — | — | — | — | 98 | — | 98 |
| Net loss | — | — | — | — | — | — | — | (1,838) | (1,838) |
| **Balance at June 30, 2020** | 3,374,560 | $ 27,651 | — | $ — | 1,538,307 | $ — | $ 206 | $ (8,053) | $ (7,847) |
| Vesting of shares of common stock subject to repurchase | — | — | — | — | 147,173 | — | — | — | — |
| Stock-based compensation | — | — | — | — | — | — | 106 | — | 106 |
| Net loss | — | — | — | — | — | — | — | (2,339) | (2,339) |
| **Balance at September 30, 2020** | 3,374,560 | $ 27,651 | — | $ — | 1,685,480 | $ — | $ 312 | $ (10,392) | $ (10,080) |
| Vesting of shares of common stock subject to repurchase | — | — | — | — | 143,897 | — | — | — | — |
| Stock-based compensation | — | — | — | — | — | — | 127 | — | 127 |
| Net loss | — | — | — | — | — | — | — | (3,685) | (3,685) |
| **Balance at December 31, 2020** | 3,374,560 | $ 27,651 | — | $ — | 1,829,377 | $ — | $ 439 | $ (14,077) | $ (13,638) |

*Continued on next page*

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| **Balance at December 31, 2020** | 3,374,560 | $ 27,651 | — | $ — | 1,829,377 | $ — | $ 439 | $ (14,077) | $ (13,638) |
| Issuance of Series A convertible preferred stock, net of issuance costs | 2,848,486 | 23,495 | — | — | — | — | — | — | — |
| Issuance of Series B convertible preferred stock, net of issuance costs | — | — | 3,874,793 | 106,128 | — | — | — | — | — |
| Issuance of common stock for stock option exercises | — | — | — | — | 139,212 | — | 86 | — | 86 |
| Vesting of shares of common stock subject to repurchase | — | — | — | — | 234,239 | — | 65 | — | 65 |
| Stock-based compensation | — | — | — | — | — | — | 174 | — | 174 |
| Net loss | — | — | — | — | — | — | — | (4,209) | (4,209) |
| **Balance at March 31, 2021** | 6,223,046 | $ 51,146 | 3,874,793 | $ 106,128 | 2,202,828 | $ — | $ 764 | $ (18,286) | $ (17,522) |
| Issuance of common stock for stock option exercises | — | — | — | — | 1,511 | — | 1 | — | 1 |
| Vesting of shares of common stock subject to repurchase | — | — | — | — | 170,012 | — | 28 | — | 28 |
| Stock-based compensation | — | — | — | — | — | — | 338 | — | 338 |
| Net loss | — | — | — | — | — | — | — | (5,512) | (5,512) |
| **Balance at June 30, 2021** | 6,223,046 | $ 51,146 | 3,874,793 | $ 106,128 | 2,374,351 | $ — | $ 1,131 | $ (23,798) | $ (22,667) |
| Preferred stock converted into shares of common stock | (6,223,046) | (51,146) | (3,874,793) | (106,128) | 26,228,089 | 3 | 157,271 | — | 157,274 |
| Initial public offering of common shares, net of issuance costs | — | — | — | — | 12,420,000 | 1 | 181,219 | — | 181,220 |
| Issuance of common stock for stock option exercises | — | — | — | — | 522 | — | 1 | — | 1 |
| Vesting of shares of common stock subject to repurchase | — | — | — | — | 184,698 | — | 39 | — | 39 |
| Stock-based compensation | — | — | — | — | — | — | 507 | — | 507 |
| Net loss | — | — | — | — | — | — | — | (6,643) | (6,643) |
| **Balance at September 30, 2021** | — | $ — | — | $ — | 41,207,660 | $ 4 | $ 340,168 | $ (30,441) | $ 309,731 |

*See accompanying notes to unaudited financial statements.*

**Tyra Biosciences, Inc.**
**Statements of Cash Flows**
(unaudited)
(in thousands)

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (16,364) | $ (5,651) |
| Adjustments to reconcile net loss to net cash used in operations: | | |
| Depreciation and amortization | 90 | 28 |
| Stock-based compensation | 1,019 | 312 |
| Change in fair value of SAFE commitments | — | 15 |
| Loss on disposal of property and equipment | 3 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | (917) | 18 |
| Accounts payable, accrued expenses and other liabilities | 1,396 | 59 |
| Right-of-use assets and lease liabilities, net | 56 | (14) |
| Net cash used in operating activities | (14,717) | (5,233) |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (556) | (245) |
| Proceeds from sale of property and equipment | 16 | — |
| Net cash used in investing activities | (540) | (245) |
| **Cash flows from financing activities:** | | |
| Proceeds from initial public offering, net of issuance costs | 182,729 | — |
| Proceeds from the issuance of Series A convertible preferred stock, net of issuance costs | 23,495 | 23,311 |
| Proceeds from the issuance of Series B convertible preferred stock, net of issuance costs | 106,128 | — |
| Proceeds from exercise of stock options | 88 | — |
| Proceeds from early exercise of stock options | 450 | 140 |
| Repayment of early exercise liability | (25) | — |
| Payments for financing lease | (9) | (13) |
| Net cash provided by financing activities | 312,856 | 23,438 |
| Net cash increase for the period | 297,599 | 17,960 |
| Cash, cash equivalents and restricted cash at beginning of the period | 15,467 | 108 |
| Cash, cash equivalents and restricted cash at end of the period | $ 313,066 | $ 18,068 |
| Reconciliation of cash, cash equivalents and restricted cash to the balance sheet | | |
| Cash and cash equivalents | $ 312,823 | $ 18,068 |
| Restricted cash | 243 | — |
| Total cash, cash equivalents and restricted cash | $ 313,066 | $ 18,068 |
| **Supplemental disclosure of cash flow information:** | | |
| Non-cash investing and financing activities: | | |
| Purchases of equipment included in accounts payable | $ 17 | $ 44 |
| Deferred issuance costs included in accounts payable and accrued expenses | 1,509 | — |
| Right-of-use asset obtained in exchange for lease liability | 1,238 | — |

*See accompanying notes to unaudited financial statements.*

## 1. Organization and Basis of Presentation

### *Organization*

Tyra Biosciences, Inc. (the "Company") was incorporated in the state of Delaware on August 2, 2018. The Company is a precision oncology company designing and developing purpose-built therapies specifically designed to overcome therapy resistance and improve the lives of cancer patients whose tumors have acquired resistance over the course of therapy to currently available treatments.

On September 17, 2021, the Company completed its initial public offering (the "IPO") and issued 12,420,000 shares of common stock for net proceeds of approximately $181.2 million. See Note 7 to these financial statements for additional details.

### *Stock Split*

On September 7, 2021, the Company effected a 2.5974-for-1 forward stock split of its common stock (the "Forward Stock Split"). The par value of the common stock was not adjusted as a result of the Forward Stock Split and the authorized shares were increased to 50,000,000 shares of common stock in connection with the Forward Stock Split. In conjunction with the Company's IPO, the authorized shares of common stock were increased to 500,000,000. The accompanying financial statements and notes to the financial statements give retroactive effect to the Forward Stock Split for all periods presented, unless otherwise indicated.

### *Basis of Presentation*

The accompanying unaudited financial statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020 have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These unaudited financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the three and nine months ended September 30, 2021 and 2020 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The balance sheet at September 30, 2021 has been derived from the financial statements at that date but does not include all disclosures required by GAAP for complete financial statements. Because all of the disclosures required by GAAP for complete financial statements are not included herein, these unaudited financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the years ended December 31, 2020 and 2019, included in the Prospectus dated September 14, 2021 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the SEC on September 15, 2021 (the "Prospectus").

### *Liquidity and Capital Resources*

From inception to September 30, 2021, the Company has devoted substantially all of its resources to organizing and staffing the company, business planning, raising capital, developing its proprietary SNÅP discovery engine, undertaking research and development activities for its development programs, establishing its intellectual property portfolio, and providing general and administrative support for its operations. The Company has a limited operating history, has never generated any revenue, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues to develop its current and future product candidates. From inception through September 30, 2021, the Company funded its operations primarily through the issuance of common stock in its IPO, the sale of convertible preferred stock and the issuance of Simple Agreements for Future Equity ("SAFEs").

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty. Management is required to perform a two-step analysis over the Company's ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2).

Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these financial statements were available to be issued. There can be no assurance that the Company will be successful in acquiring additional funding (if needed), that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

**2. Summary of Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the audited financial statements for the years ended December 31, 2020 and 2019, included in the Prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies, except as noted below.

***Commitments and Contingencies***

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of September 30, 2021 and December 31, 2020.

***Related Parties***

Transactions between related parties are considered to be related party transactions even though they may not be given accounting recognition. Financial Accounting Standards Board ("FASB") ASC 850, Related Party Disclosures ("FASB ASC 850") requires that transactions with related parties that would make a difference in decision making shall be disclosed so that users of the financial statements can evaluate their significance. Related party transactions typically occur within the context of the following relationships:

- Affiliates of the entity;
- Entities for which investments in their equity securities is typically accounted for under the equity method by the investing entity;
- Trusts for the benefit of employees;
- Principal owners of the entity and members of their immediate families;
- Management of the entity and members of their immediate families;
- Other parties that can significantly influence the management or operating policies of the transacting parties and can significantly influence the other to an extent that one or more of the transacting parties might be prevented from fully pursuing its own separate interests.

The Company previously entered into a consulting agreement with van den Boom & Associates, LLC ("van den Boom & Associates"), a professional services firm contracted to provide resources to assist with day-to-day accounting functions. Services provided under the agreement with van den Boom & Associates are billed at hourly rates. On April 16, 2021, Ms. van den Boom, the managing partner of van den Boom & Associates, entered into an employment agreement with the Company whereby she became its Chief Financial Officer. van den Boom & Associates is considered a related party under FASB ASC 850 from the point in which Ms. van den Boom became a Company officer. During the date of her employment agreement to September 30, 2021, van den Boom & Associates rendered contracted services totaling approximately $0.4 million.

***Recently Issued Accounting Pronouncements***

There were no other significant updates not already disclosed in the Company's audited financial statements for the years ended December 31, 2020 and 2019 to the recently issued accounting standards for the three and nine months ended September 30, 2021. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

**3. Fair Value Measurements**

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

**Level 1**—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

**Level 2**—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

**Level 3**—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. Included in cash and cash equivalents at September 30, 2021 and December 31, 2020 are money market funds with a carrying value and fair value of $302.3 million and $4.7 million, respectively, based upon a Level 1 fair value assessment.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

**4. Property and Equipment**

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Equipment | $ 628 | $ 293 |
| Computers and software | 72 | 33 |
| Leasehold improvements | 122 | — |
| Furniture and fixtures | 76 | 14 |
| | 898 | 340 |
| Less: accumulated depreciation | (119) | (43) |
| Total property and equipment, net | $ 779 | $ 297 |

Depreciation expense for the three and nine months ended September 30, 2021 was $41,000 and $90,000, respectively. Depreciation expense for the three and nine months ended September 30, 2020 was $16,000 and $28,000, respectively.

**5. Accrued and Other Current Liabilities**

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Accrued payroll and other employee benefits | $ 634 | $ 774 |
| Accrued research and development | 392 | 163 |
| Accrued legal and professional fees | 1,356 | 67 |
| Accrued other general and administrative fees | 183 | 48 |
| Total accrued and other current liabilities | $ 2,565 | $ 1,052 |

**6. Simple Agreements for Future Equity**

During 2018 and 2019, the Company entered into SAFEs with investors. The SAFEs granted investors with rights to participate in a future equity financing. The SAFEs contained a number of conversion and redemption provisions, including conversion upon an equity event, and settlement upon liquidity or dissolution events. The Company elected the fair value option of accounting for the SAFEs. The issuance costs related to the SAFEs were recorded as a general and administrative expense in the Statements of Operations and Comprehensive Loss. On January 6, 2020, the Company entered into a Series A Preferred Stock Purchase agreement which provided for the conversion of the outstanding SAFEs into 526,074 shares of Series A convertible preferred stock at a conversion price of $6.11 per share.

**7. Convertible Preferred Stock and Stockholders' Deficit**

***Stockholders' Deficit***

Under the Amended and Restated Certificate of Incorporation dated September 17, 2021, the Company had a total of 550,000,000 shares of capital stock authorized for issuance, consisting of 500,000,000 shares of common stock, par value of $0.0001 per share, and 50,000,000 shares of preferred stock, par value of $0.0001 per share.

***Convertible Preferred Stock***

The Company entered into the Series A Preferred Stock Purchase Agreement dated January 6, 2020 ("Stock Purchase Agreement") whereby the Company agreed to issue and sell, and certain investors agreed to purchase up to an aggregate of 5,696,972 shares of Series A convertible preferred stock, at a price of $8.25 per share, in two closings. In January 2020, the Company completed its first closing and issued 2,848,486 shares at a price of $8.25 per share resulting in gross proceeds of $23.5 million and incurred issuance costs of $0.2 million. The Stock Purchase Agreement granted investors the rights and obligations to purchase an additional 2,848,486 shares of Series A convertible preferred stock ("Future Tranche Right") at a price of $8.25 per share during a second closing which would occur upon triggering of future milestone events, provided that they occur before January 6, 2022. In February 2021, the Company completed its second closing and issued 2,848,486 shares of Series A convertible preferred stock at a price of $8.25 per share for gross proceeds of $23.5 million and incurred issuance costs of $5,000.

The Company determined that the Future Tranche Right did not meet the definition of a freestanding financial instrument as it was not legally detachable. The Future Tranche Right was also evaluated as an embedded derivative and the Company determined it did not meet the definition of a derivative instrument for which bifurcation would be required.

In March 2021, the Company entered into the Series B Preferred Stock Purchase Agreement under which it issued 3,874,793 shares of Series B convertible preferred stock, at a price of $27.4337 per share, resulting in net proceeds of $106.1 million excluding issuance costs of $0.2 million.

On September 17, 2021, upon completion of the IPO, the Company sold 12,420,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,620,000 additional shares at a public offering price of $16.00 per share and all of the Company's shares of convertible preferred stock converted into 26,228,089 shares of common stock.

***Common Stock***

As of September 30, 2021 and December 31, 2020, of the 500,000,000 and 50,000,000 authorized shares of common stock, respectively, 42,535,661 and 3,050,781 shares were issued, respectively, and 41,207,660 and 1,829,377 shares were outstanding, respectively.

The voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the Series A convertible preferred stock outstanding at December 31, 2020. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Convertible preferred stock | — | 8,765,053 |
| Common stock options granted and outstanding | 2,586,313 | 1,374,714 |
| Shares available for future issuance under the 2020 equity incentive plan | — | 28,595 |
| Shares available for future issuance under the 2021 equity incentive plan | 10,570,000 | — |
| Shares available for future issuance under the 2021 Employee Stock Purchase Plan | 1,200,000 | — |
| Total common stock reserved for future issuance | 14,356,313 | 10,168,362 |

***Restricted Stock***

Since inception, the Company has issued 2,820,560 shares of restricted common stock at a price of $0.0001 per share to certain founders of the Company (“Founders Stock”). The Company maintains a repurchase right whereby the Founders Stock are released from such repurchase right over a period of time of continued service by the recipient. Any shares subject to repurchase by the Company are not deemed, for accounting purposes, to be outstanding until those shares vest. Unvested outstanding Founders Stock as of September 30, 2021 and December 31, 2020 were 619,069 and 991,178 shares, respectively. The amount recorded as liabilities associated with shares issued with repurchase rights were immaterial as of September 30, 2021 and December 31, 2020.

In January 2020, in connection with the issuance of the Series A convertible preferred stock, the Company’s founders agreed to modify their outstanding Founders Stock to include vesting provisions that require continued service to the Company in order to vest in those shares. As such, the 1,461,816 modified shares of common stock became compensatory upon such modification. The total compensation cost resulting from the modification was $0.9 million, which will be recognized over the vesting term of three years had a measurement date fair value of $0.61 per share. For the nine months ended September 30, 2021 and 2020, 365,445 shares vested in each period and the Company recognized $0.2 million of stock-based compensation expense for each period related to the awards. As of September 30, 2021, the total unrecognized compensation expense related to unvested Founders Stock was $0.4 million expected to be recognized over a weighted-average period of approximately 1.3 years.

***Stock Options***

In January 2020, the Company adopted the 2020 Equity Incentive Plan (the “2020 Plan”). The 2020 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards. The 2020 Plan was amended in March 2021 to increase the total number of shares reserved under the Plan to 4,685,475.

In September 2021, the Company's Board of Directors adopted, and its stockholders approved, the 2021 Incentive Award Plan (the “2021 Plan”). Upon the adoption of the 2021 Plan, the Company restricted the grant of future equity awards under its 2020 Plan.

The 2021 Plan provides for the grants of stock options and other equity-based awards to employees, non-employee directors, and consultants of the Company. A total of 5,570,000 shares of the Company’s common stock were initially reserved for issuance pursuant to the 2021 Plan. The number of shares reserved under the 2021 Plan also included 1,032,150 shares of the Company’s common stock that remained available for issuance under the 2020 Plan as of immediately prior to the effectiveness of the 2021 Plan. The 2021 Plan share reserve will be increased by the number of shares under the 2020 Plan that are repurchased, forfeited, expired or cancelled after the effective date of the 2021 Plan. In addition, the number of shares of the Company’s common stock available for issuance under the 2021 Plan will automatically increase on the first day of each fiscal year, beginning with the Company’s 2022 fiscal year, in an amount equal to the lessor of (1) 5% of the outstanding shares of the Company’s common stock on the last day of the immediately preceding fiscal year, or (2) such smaller amount as determined by the Company’s Board of Directors.

Options granted under the 2020 Plan and the 2021 Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option shall be determined by the Company’s Board of Directors based on the fair market value of the Company’s stock on the date of the option grant. The exercise price shall not be less than 100% of the fair market value of the Company’s common stock at the time the option is granted. Most option grants generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years and early exercise is permitted. The vesting period generally occurs over four years unless there is a specific performance vesting trigger at which time those shares will vest when the performance trigger is probable to occur.

A summary of the Company's stock option activity for the nine months ended September 30, 2021 is as follows (in thousands, except share amounts):

| | Options | Weighted-Average Exercise Price per Share | Weighted-Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2020 | 1,374,714 | $ 0.61 | 9.4 | $ — |
| Granted | 2,088,932 | $ 3.42 | | |
| Exercised | (877,333) | $ 0.61 | | $ 292 |
| Outstanding at September 30, 2021 | 2,586,313 | $ 2.88 | 9.3 | $ 38,044 |
| Exercisable at September 30, 2021 | 742,432 | $ 1.25 | 8.9 | $ 12,128 |
| Vested and expected to vest as of September 30, 2021 | 2,573,687 | $ 2.89 | 9.3 | $ 37,841 |

For the nine months ended September 30, 2021 and 2020, the total grant date fair value of vested options was $0.6 million and $17,000, respectively.

The weighted-average grant date fair value of employee option grants for the nine months ended September 30, 2021 and 2020 was $2.70 and $0.47 per share, respectively.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants issued during the nine months ended September 30, 2021 and 2020 were as follows:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| **Stock Options:** | | |
| Stock price | $0.99 - 16.00 | $0.61 |
| Risk-free rate of interest | 0.8 - 1.1% | 0.3 - 1.5% |
| Expected term (years) | 5.0 - 6.1 | 5.7 - 6.1 |
| Expected stock price volatility | 98.9 - 99.9% | 92.9 - 97.5% |
| Dividend yield | — | — |

As of September 30, 2021, the unrecognized compensation cost related to outstanding employee and nonemployee options was $5.4 million, and is expected to be recognized as expense over a weighted-average period of approximately 3.8 years.

***Liability for Early Exercise of Stock Options***

Certain individuals were granted the ability to early exercise their stock options. The shares of common stock issued from the early exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees and non-employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. The cash received in exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock options on the accompanying balance sheets and will be transferred into common stock and additional paid-in capital as the shares vest. As of September 30, 2021 and December 31, 2020, 749,476 and 230,222 unvested shares issued under early exercise provisions were subject to repurchase by the Company, respectively. As of September 30, 2021 and December 31, 2020, the Company recorded $0.4 million and $0.1 million, respectively, associated with shares issued with repurchase rights in other long-term liabilities.

***Employee Stock Purchase Plan***

In September 2021, the Company's Board of Directors adopted the 2021 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with the IPO. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation, not to exceed $25,000 or 100,000 shares in a calendar year. A total of 380,000 shares of common stock was initially reserved for issuance under the ESPP. In addition, the number of shares of the Company's common stock available for issuance under the ESPP will automatically increase on the first day of each fiscal year, beginning with the Company's 2022 fiscal year, in an amount equal to the lessor of (1) 1% of the outstanding shares of the Company's common stock on the last day of the immediately preceding fiscal year, or (2) such smaller amount as determined by the Company's Board of Directors. There were no shares issued under the ESPP during the three and nine months ended September 30, 2021.

***Stock-Based Compensation Expense***

The Company recognized stock-based compensation expense of $0.2 million and $0.4 million in research and development expense during the three and nine months ended September 30, 2021 and $0.3 million and $0.6 million in general and administrative expense during the three and nine months ended September 30, 2021, respectively. The Company recognized stock-based compensation expense of $0 million and $0.1 million in research and development expense during the three and nine months ended September 30, 2020 and $0.1 million and $0.2 million in general and administrative expense during the three and nine months ended September 30, 2020, respectively.

**8. Net Loss Per Share**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Numerator: | | | | |
| Net loss | $ (6,643) | $ (2,339) | $ (16,364) | $ (5,651) |
| Denominator: | | | | |
| Weighted average common shares outstanding | 10,621,868 | 3,052,395 | 5,984,285 | 2,927,056 |
| Less: weighted average unvested founder shares of common stock | (673,607) | (1,227,301) | (785,036) | (1,345,303) |
| Less: weighted average unvested common stock issued upon early exercise of common stock options | (784,258) | (230,221) | (694,252) | (106,487) |
| Weighted average shares used to compute net loss per common share, basic and diluted | 9,164,003 | 1,594,873 | 4,504,997 | 1,475,266 |
| Net loss per share, basic and diluted | $ (0.72) | $ (1.47) | $ (3.63) | $ (3.83) |

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive.

| | As of September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Convertible preferred stock | — | 2,848,486 |
| Unvested restricted common stock subject to repurchase | 619,069 | 1,135,078 |
| Unvested common stock upon early exercise of stock options | 749,476 | 230,222 |
| Options to purchase common stock | 2,586,313 | 930,926 |
| | 3,954,858 | 5,144,712 |

**9. License Agreement**

In May 2019, the Company entered into a license agreement (the "License Agreement") with Emory University ("Emory") to obtain rights to certain know-how, patents, and patent applications to pursue the development and commercialization of certain inventions and technology for the treatment of disease. In February 2021, the Company provided 90-day notice to Emory of their decision to voluntarily terminate the License Agreement. There were no milestones payments met or paid in the nine months ended September 30, 2021.

**10. Leases**

In August 2020, the Company entered into an operating lease for office and lab space in Carlsbad, California (the "Carlsbad Lease"). The Carlsbad Lease has a lease term of 60 months from the contractual lease commencement date. The Company has the option to renew the lease for two additional thirty-six-month periods. As of September 30, 2021, the underlying asset was made available for use by the Company and therefore, the Carlsbad Lease is considered to have commenced. The Company recognized an initial right-of-use asset and lease liability of $1.2 million, respectively, for the lease. The initial right-of-use asset was calculated based on the initial lease term of 60 months, as the renewal options were not reasonably certain of being exercised. As the Carlsbad Lease did not provide an implicit rate, the Company used an estimated incremental borrowing rate of 7.5%, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment.

In conjunction with the Carlsbad Lease, the Company paid a cash security deposit of $21,000, of which all is refundable at the end of the lease term and is included in long-term assets in the Company's balance sheet as of September 30, 2021. Additionally, as part of the terms of the lease agreement, the Company was required to maintain a letter of credit of $0.2 million which must remain in place until 2023 at the earliest and was considered a non-current asset as of September 30, 2021.

The following table presents the balances for operating and finance leases ROU assets and lease liabilities (in thousands):

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Operating lease assets | $ 1,129 | $ 148 |
| Finance lease assets | — | 21 |
| Total lease assets | $ 1,129 | $ 169 |
| | | |
| **Liabilities** | | |
| Operating lease liabilities, current | $ 135 | $ 133 |
| Operating lease liabilities, noncurrent | 1,037 | — |
| Finance lease liabilities, current | — | 9 |
| Total lease liabilities | $ 1,172 | $ 142 |

The components of lease expense include operating and finance lease costs. Amortization is recorded in research and development expenses and interest expense is recorded in other expenses in the Statements of Operations and Comprehensive Loss. Components of lease cost for the three and nine months ended September 30, 2021 and 2020 were as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Operating lease cost | $ 124 | $ 27 | $ 251 | $ 76 |
| Finance lease cost | | | | |
| Amortization of ROU assets | 1 | 2 | 5 | 6 |
| Interest on lease liabilities | — | — | — | 1 |

Maturities of lease liabilities, weighted-average remaining term and weighted-average discount rate were as follows (in thousands):

| | As of September 30, |
|---|---|
| Year ending December 31, | |
| 2021 (remaining three months) | $ 20 |
| 2022 | 277 |
| 2023 | 299 |
| 2024 | 308 |
| 2025 | 318 |
| Thereafter | 188 |
| Total minimum lease payments | 1,410 |
| Less: amount representing interest | (238) |
| Present value of lease liabilities | 1,172 |
| Less: current portion of lease liabilities | (135) |
| Lease liabilities, noncurrent | $ 1,037 |

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Weighted-average remaining lease term (years) - operating leases | 4.8 | 0.8 |
| Weighted-average remaining lease term (years) - finance leases | 0.0 | 0.6 |
| Weighted-average incremental borrowing rate - operating leases | 7.50% | 7.50% |
| Weighted-average incremental borrowing rate - finance leases | 7.50% | 7.50% |

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

*The following discussion and analysis and the unaudited interim financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Prospectus dated September 14, 2021 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (SEC) on September 15, 2021 (the Prospectus).*

**Forward-Looking Statements**

This Quarterly Report on Form 10-Q (Quarterly Report) contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned preclinical studies and planned clinical trials for our product candidates, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, the impact of the COVID-19 pandemic on our business, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "continue" "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target" or "will" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including, without limitation, the risk factors described in Part II, Item 1A, "Risk Factors" of this Quarterly Report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

**Overview**

We are a precision oncology company focused on developing purpose-built therapies to overcome tumor resistance and improve outcomes for patients with cancer. We are using our proprietary SNÅP platform, which is optimized to enable rapid and precise refinement of structural design through iterative molecular SNÅPshots, in order to generate next-generation product candidates that are specifically designed to address acquired drug resistance and provide alternative treatment options. We are initially focused on developing a pipeline of selective inhibitors of the Fibroblast Growth Factor Receptor (FGFR) family members, which are altered in approximately 7% of all cancers. We are advancing multiple product candidates toward the clinic including our lead product candidate TYRA-300, an FGFR3 inhibitor with an initial focus on patients with bladder cancer, and TYRA-200, an FGFR2 inhibitor with an initial focus on patients with intrahepatic cholangiocarcinoma who have developed drug resistance mutations from existing FGFR therapies. We anticipate filing an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration (FDA) for TYRA-300 in mid-2022 and we anticipate filing an IND with the FDA for TYRA-200 in the second half of 2022. In addition, we have pipeline development programs targeting FGFR3-related achondroplasia, REarranged during Transfection kinase, or RET, and FGFR4-related cancers.

Since the commencement of our operations in 2018, we have devoted substantially all of our resources to organizing and staffing the company, business planning, raising capital, developing our proprietary SNÅP platform, undertaking research and development activities for our development programs, establishing our intellectual property portfolio, and providing general and administrative support for our operations. We have not generated any revenue to date and have funded our operations primarily from our initial public offering (IPO), private placements of our convertible preferred stock, and the issuance of Simple Agreement for Future Equity (SAFEs). Our net losses for the nine months ended September 30, 2021 and 2020 were $16.4 million and $5.7 million, respectively. As of September 30, 2021, we had an accumulated deficit of $30.4 million. As of September 30, 2021, we had cash and cash equivalents of $312.8 million.

We have incurred significant operating losses since inception. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and capital expenditures. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future particularly if and as we conduct preclinical studies and planned clinical trials, continue our research and development activities, utilize third parties to manufacture our product candidates and related raw materials, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company.

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditures through at least 2024. We have never generated any revenue and do not expect to generate any revenues from product sales unless and until we successfully complete development of and obtain regulatory approval for our product candidates, which will not be for several years, if ever. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. If we are unable to raise additional capital or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

The global COVID-19 pandemic continues to evolve, and we will continue to monitor the COVID-19 situation closely. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the pandemic and its impact on our development activities, contract research organizations, or CROs, third-party manufacturers and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel.

**Components of Results of Operations**

***Operating Expenses***

*Research and Development Expenses*

To date, our research and development expenses consist primarily of external and internal costs related to the development of our SNÅP platform and our product candidates and development programs. Our research and development expenses primarily include:

- external costs, including:
  - expenses incurred in connection with the discovery and preclinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
  - costs associated with consultants for chemistry, manufacturing and controls, or CMC development, and other services;
  - the cost of manufacturing compounds for use in our preclinical studies, including under agreements with third parties, such as consultants and third-party manufacturers;
- internal costs, including:
  - employee-related expenses, including salaries, related benefits, travel and share-based compensation expenses for employees engaged in research and development functions;
  - the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study materials; and
  - facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, and supplies.

We expense research and development expenses in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external expenses on a development program and other program specific basis. However, we do not track internal costs on a program specific basis because these costs primarily relate to compensation, early research and consumable costs, which are deployed across multiple programs under development.

Research and development activities are central to our business model. There are numerous factors associated with the successful development of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of development generally have higher development costs than those in earlier stages of development. As a result, we expect that our research and development expenses will increase substantially over the next several years as we advance our product candidates through preclinical studies into and through clinical trials, continue to discover and develop additional product candidates and expand our pipeline, maintain, expand, protect and enforce our intellectual property portfolio, and hire additional personnel.

Our future research and development expenses may vary significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of our discovery and preclinical development activities and clinical trials;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any;
- the cost and timing of manufacturing our product candidates;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of the COVID-19 pandemic environment; and
- the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates or any future candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our product candidates or any future candidates.

*General and Administrative Expenses*

General and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, and stock-based compensation charges, for personnel in executive and administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, tax and consulting services and insurance costs. We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities, manufacturing activities, and the increased costs associated with operating as a public company. These increased costs will likely include increased expenses related to hiring of additional personnel, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC, requirements, director and officer insurance costs, and investor and public relations costs.

***Change in Fair Value of SAFEs***

We issued SAFEs in 2019 and 2018 for which we have elected to account for using the fair value option. We adjust the carrying value of our SAFEs to their estimated fair value at each reporting date, with any change in fair value of the SAFE recorded as an increase or decrease to change in fair value of simple agreement for future equity in our statement of operations and comprehensive loss.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2021 and 2020***

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

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2021 | 2020 | Change |
| Operating expenses: | | | |
| Research and development | $ 5,484 | $ 1,862 | $ 3,622 |
| General and administrative | 1,154 | 470 | 684 |
| Total operating expenses | 6,638 | 2,332 | 4,306 |
| Loss from operations | (6,638) | (2,332) | (4,306) |
| Other (expense) income: | | | |
| Interest income | 2 | 0 | 2 |
| Other expense | (7) | (7) | 0 |
| Total other expense | (5) | (7) | 2 |
| Net loss and comprehensive loss | $ (6,643) | $ (2,339) | $ (4,304) |

***Research and Development Expenses***

Research and development expenses were $5.5 million and $1.9 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $3.6 million was primarily due to additional spend to support the advancement of our TYRA-300 and other development programs, including preclinical studies and chemistry. Further, we incurred $0.6 million higher personnel-related costs in the three months ended September 30, 2021 as compared to 2020, as we continued to expand the number of research and development employees to support our programs, including an additional $0.2 million of non-cash stock-based compensation costs.

The following table summarizes our research and development expenses by development program for the three months ended September 30, 2021 and 2020 (in thousands):

| | Three Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| External research and development expense by program | | |
| TYRA-300 | $ 1,786 | $ 1,107 |
| Other development programs | 2,253 | 184 |
| Unallocated research and development expense | | |
| Other research and development | 411 | 170 |
| Compensation and stock-based compensation | 1,033 | 401 |
| Total research and development expense | $ 5,484 | $ 1,862 |

***General and Administrative Expenses***

General and administrative expenses were $1.2 million and $0.5 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $0.7 million was primarily due to an increase of $0.6 million in personnel-related expenses including $0.2 million in non-cash stock-based compensation costs, and $0.1 million in professional services related to legal, accounting services, and other consulting fees.

***Comparison of the Nine Months Ended September 30, 2021 and 2020***

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

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2021 | 2020 | Change |
| Operating expenses: | | | |
| Research and development | $ 13,386 | $ 4,275 | $ 9,111 |
| General and administrative | 2,970 | 1,345 | 1,625 |
| Total operating expenses | 16,356 | 5,620 | 10,736 |
| Loss from operations | (16,356) | (5,620) | (10,736) |
| Other (expense) income: | | | |
| Interest income | 8 | 1 | 7 |
| Change in fair value of SAFE commitments | — | (15) | 15 |
| Other expense | (16) | (17) | 1 |
| Total other expense | (8) | (31) | 23 |
| Net loss and comprehensive loss | $ (16,364) | $ (5,651) | $ (10,713) |

***Research and Development Expenses***

Research and development expenses were $13.4 million and $4.3 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of $9.1 million was primarily due to additional spend to support the advancement of our TYRA-300 and other development programs in 2021, including preclinical studies and chemistry. Further, we incurred $1.9 million higher personnel-related costs in the first nine months of 2021 as compared to 2020, as we expanded the number of research and development employees to support our programs, including an additional $0.3 million of non-cash stock-based compensation costs.

The following table summarizes our research and development expenses by development program for the nine months ended September 30, 2021 and 2020 (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| External research and development expense by program | | |
| TYRA-300 | $ 4,604 | $ 2,422 |
| Other development programs | 4,824 | 285 |
| Unallocated research and development expense | | |
| Other research and development | 931 | 442 |
| Compensation and stock-based compensation | 3,026 | 1,126 |
| Total research and development expense | $ 13,386 | $ 4,275 |

***General and Administrative Expenses***

General and administrative expenses were $3.0 million and $1.3 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of $1.7 million was primarily due to increases of $0.8 million in professional services related to legal, accounting services, and other consulting fees and $0.6 million in personnel-related expenses, including $0.4 million in non-cash stock-based compensation costs.

***Change in Fair Value of Simple Agreement for Future Equity***

Change in fair value of SAFE was $15,000 for the nine months ended September 30, 2020. The SAFEs were converted to Series A convertible preferred stock in January 2020.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since our inception, we have not generated any milestone or commercial revenue and have incurred net losses and negative cash flows from our operations. We have financed our operations since our inception with $355.9 million in gross proceeds raised primarily from our IPO, private placements of convertible preferred stock, and the issuance of SAFEs.

In January 2020, we issued and sold an aggregate of 2,848,486 Series A preferred shares at a price per share of $8.25 for aggregate cash consideration of approximately $23.5 million. In February 2021, we issued and sold an aggregate of 2,848,486 Series A preferred shares at a price per share of $8.25 for aggregate cash consideration of approximately $23.5 million.

In March 2021, we issued and sold an aggregate of 3,874,793 Series B preferred shares at a price per share of $27.4337 for aggregate cash consideration of approximately $106.3 million.

On September 17, 2021, we completed our IPO and issued 12,420,000 shares of common stock for net proceeds of approximately $181.2 million. As of September 30, 2021, we had cash and cash equivalents of $312.8 million.

***Cash Flows***

The following table sets forth a summary of our cash flows for the periods indicated (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Net cash used in operating activities | $ (14,717) | $ (5,233) |
| Net cash used in investing activities | (540) | (245) |
| Net cash provided by financing activities | 312,856 | 23,438 |
| Net cash increase for the period | $ 297,599 | $ 17,960 |

*Operating Activities*

Net cash used in operating activities for the nine months ended September 30, 2021 was $14.7 million, consisting primarily of our net loss of $16.4 million, adjusted for $1.1 million of non-cash charges and $0.6 million for net changes in operating assets and liabilities. Noncash charges consisted primarily of $1.0 million of stock-based compensation. The net change in operating assets and liabilities was primarily related to a $0.9 million decrease in prepaid expenses and other assets and a $1.4 million increase in accounts payable and accrued liabilities.

Net cash used in operating activities for the nine months ended September 30, 2020 was $5.2 million, consisting primarily of our net loss of $5.7 million, adjusted for $0.4 million of non-cash charges and $0.1 million for net changes in operating assets and liabilities. Non-cash charges consisted primarily of $0.3 million of stock-based compensation expense in addition to depreciation expense and amortization. The net change in operating assets and liabilities was primarily related to $0.1 million increase in accounts payable and accrued liabilities with offsetting increases and decreases to prepaid expenses and other assets and right-of-use assets and lease liabilities, net.

*Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2021 and 2020 was $0.5 million and $0.2 million, respectively, consisting of purchases of property and equipment.

*Financing Activities*

Net cash provided by financing activities was $312.9 million for the nine months ended September 30, 2021 and was primarily related to net proceeds of $182.7 from our IPO, net of issuance costs, in addition to net proceeds of $23.5 million from the second closing of our Series A convertible preferred stock, $106.1 million in net proceeds from the issuance of our Series B convertible preferred stock, and $0.6 million from proceeds received from the exercise of stock options.

Net cash provided by financing activities was $23.4 million for the nine months ended September 30, 2020, primarily related to net proceeds of $23.3 million from the issuance of Series A convertible preferred stock, and $0.1 million from proceeds received from the exercise of stock options.

***Future Funding Requirements***

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to meet our anticipated operating expenses and capital expenditures through at least 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain.

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

- the initiation, type, number, scope, results, costs and timing of, our ongoing and planned preclinical studies and clinical trials of existing product candidates or clinical trials of other potential product candidates we may choose to pursue in the future, including based on feedback received from regulatory authorities;
- the costs and timing of manufacturing for current or future product candidates, including commercial scale manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of current or future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel;

- the costs and timing of establishing or securing sales and marketing capabilities if any current or future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- costs associated with any products or technologies that we may in-license or acquire; and
- delays or issues with any of the above, including the risk of each of which may be exacerbated by the ongoing COVID-19 pandemic.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

**Critical Accounting Policies**

There have been no material changes to our critical accounting policies and estimates during the three and nine months ended September 30, 2021, as compared to the critical accounting policies and estimates disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Note 2 to our financial statements for the year ended December 31, 2020 included in the Prospectus.

**Recently Adopted Accounting Pronouncements**

See Note 2 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q for recently issued accounting pronouncements that may potentially impact our financial position and results of operations.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As of September 30, 2021, there have been no material changes surrounding our market risk, including interest rate risk, foreign currency exchange risk, and inflation risk, from the discussion provided in “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Quantitative and Qualitative Disclosures about Market Risk” in the Prospectus.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

**Changes in Internal Control Over Financial Reporting**

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ended December 31, 2021. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

### Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information included in this Quarterly Report and in the Prospectus, including our financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision to purchase or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. The risks described below are not the only ones that we may face, and additional risks or uncertainties not known to us or that we currently deem immaterial may also impair our business and future prospects.

### Summary of Risks Related to Our Business

The risk factors included below are a summary of the principal risk factors associated with an investment in us. The summary below does not contain all of the risks we face. You should carefully consider this summary, together with the more detailed discussion of these risks and uncertainties set forth below in this Item 1A.

- We are very early in our development efforts, have a limited operating history, have not initiated or completed any clinical trials, have no products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses in each period since our inception, and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to discovery, development and commercialization of our product candidates.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We are early in our development efforts and all of our development programs are in the preclinical or discovery stage. If we are unable to successfully develop, obtain marketing approval and ultimately commercialize product candidates, or experience significant delays in doing so, our business will be materially harmed.
- As an organization, we have never conducted any clinical trials or submitted an application for marketing approval, and may be unable to do so for any of our product candidates.
- Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. We have not tested any of our product candidates in clinical trials and our product candidates may not have favorable results in clinical trials, if any, or receive marketing approval on a timely basis, if at all.
- We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.
- We intend to rely on third parties for the manufacture of our product candidates for preclinical and clinical development. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- We rely on third parties to conduct some of our preclinical studies and will rely on third parties to conduct our future clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain marketing approval for or commercialize our product candidates may be delayed.
- We face significant competition, and, if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.
- Our business is subject to risks arising from COVID-19 and other epidemic diseases.
- If we are unable to obtain and maintain patent protection for our product candidates and other proprietary technologies we develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and other proprietary technologies we may develop may be adversely affected.
- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

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

***We are very early in our development efforts, have limited operating history, have not initiated or completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.***

Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. We are a preclinical-stage biopharmaceutical company formed in 2018 with a limited operating history upon which you can evaluate our business and prospects. Our development programs, including our lead product candidate, TYRA-300 and our FGFR2 product candidate, TYRA-200, are either in preclinical development or in the drug discovery stage. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, research and development activities including development of our proprietary SNÅP platform and identifying potential product candidates, establishing our intellectual property portfolio, conducting research and preclinical studies, and providing general and administrative support to these operations. Our approach to the discovery and development of product candidates based on our proprietary SNÅP platform is unproven, and we do not know whether we will be able to develop any product candidates that are successful in clinical development or products of commercial value.

As an organization, we have not yet initiated or completed any clinical trials, obtained regulatory approvals, manufactured a commercial-scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

***We have incurred significant net losses in each period since our inception, and we expect to continue to incur significant net losses for the foreseeable future.***

We have incurred significant operating losses since our inception. Our net losses were $6.6 million and $2.3 million for the three months ended September 30, 2021 and 2020, respectively, and $16.4 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $30.4 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. TYRA-300, TYRA-200 and any of our other product candidates will require substantial additional development time and resources before we are able to apply for, or receive, marketing approval and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, and seek marketing approval for, and potentially commercialize any of our product candidates and as we seek to discover, develop and market additional potential product candidates.

***Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to discovery, development and commercialization of our product candidates.***

To generate revenue and achieve profitability, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including identifying lead product candidates, completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We are only in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates do, we may never

generate revenues that are significant or large enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we obtain marketing approval for one or more of our product candidates and achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies for our development programs, initiate clinical trials for our product candidates and seek marketing approval for our current product candidates and any future product candidates we may develop. If we obtain marketing approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operations through at least 2024. In particular, we expect that our existing cash and cash equivalents will allow us to complete the Phase 1 portion of our planned Phase 1/2 clinical trial for TYRA-300 and Phase 1 clinical development for TYRA-200, and advance our FGFR3 program into the clinic. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially additional collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

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

- the type, number, scope, progress, expansions, results, costs and timing of, discovery, preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates and commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational, compliance, and quality systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved for commercial sale;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;

- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approval;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Because we do not expect to generate commercial revenues, if any, from sales of products that we do not expect to be commercially available for many years, if at all, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Any future debt financing and preferred equity financing, if available, may involve, agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

**Risks Related to the Discovery, Development and Marketing Approval of Our Product Candidates**

***We are early in our development efforts and all of our development programs are in the preclinical or discovery stage. If we are unable to successfully develop, obtain marketing approval and ultimately commercialize product candidates, or experience significant delays in doing so, our business will be materially harmed.***

We are in the early stages of our research and development efforts and all of our development programs, including TYRA-300 and TYRA-200, are either in the preclinical or drug discovery stage. We have invested substantially all of our efforts to date in developing our proprietary SNÅP platform, developing TYRA-300 and TYRA-200, identifying other potential product candidates and conducting preclinical studies. We will need to progress TYRA-300, TYRA-200 and our other product candidates through additional preclinical studies to enable us to submit Investigational New Drug applications, or INDs, with the U.S. Food and Drug Administration, or the FDA, and receive clearance from the FDA to proceed with initiating their clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies with favorable results, including those compliant with Good Laboratory Practice, or GLP, such as toxicology studies, biodistribution studies and minimum effective dose studies in animals;
- acceptance by the FDA of INDs or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of TYRA-300, TYRA-200 and our other product candidates and our proposed design of future clinical trials;
- successful enrollment in clinical trials and completion of clinical trials with favorable results;
- successful identification of new product candidates utilizing our SNÅP platform;
- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;

- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;

- receipt of marketing approvals from applicable regulatory authorities, including new drug applications, or NDAs, from the FDA and maintaining such approvals;

- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;

- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;

- maintaining an acceptable safety profile of our products following marketing approval, including acceptable results from any post-approval studies or clinical trials agreed to by us or required by the FDA; and

- maintaining and growing an organization of people who can develop and commercialize our product candidates.

The FDA or comparable foreign regulatory authorities can refuse to accept INDs or similar regulatory submissions for many reasons, including negative or ambiguous results from our preclinical studies or disagreement with our interpretation of data from preclinical studies. If we are unable to develop, obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

***As an organization, we have never conducted any clinical trials or submitted an application for marketing approval, and may be unable to do so for any of our product candidates.***

We are early in our development efforts for our product candidates and we will need to successfully complete IND-enabling studies, Phase 1 clinical trials and later-stage and pivotal clinical trials, in order to obtain marketing authorization from the FDA or comparable foreign regulatory authorities to market TYRA-300, TYRA-200 or any other product candidates. Carrying out clinical trials and the submission of a successful NDA is a complicated process. As an organization, we plan to commence our first Phase 1/2 clinical trial in the second half of 2022, subject to receiving clearance to proceed under an IND. We have not previously conducted any clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an IND or an NDA or other comparable foreign regulatory submission for any product candidate. If we decide to develop TYRA-300 or TYRA-200 for multiple indications, we may be required to submit multiple INDs to the FDA for these indications and may not conduct a clinical trial in the United States for that indication until we do so. In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of TYRA-300, TYRA-200 or any other product candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from, or delay us in submitting NDAs for, and commercializing our product candidates.

***Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. We have not tested any of our product candidates in clinical trials and our product candidates may not have favorable results in clinical trials, if any, or receive marketing approval on a timely basis, if at all.***

Preclinical and clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and delay or failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any biopharmaceutical company's product candidate can unexpectedly fail at any stage of preclinical or clinical development, and regulators, such as the FDA or comparable foreign regulatory authorities, may not accept the results as demonstrating the product candidate's safety and efficacy. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted certain preclinical studies of TYRA-300, TYRA-200 and other potential product candidates targeting acquired resistance mutations in FGFR3, RET, and FGFR4, we do not know whether TYRA-300, TYRA-200 or the other potential product candidates will perform in future clinical trials as they have performed in these prior studies. The positive results we have observed for our product candidates in preclinical animal models may not be predictive of our future clinical trials in humans. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very

promising early results. We are currently conducting IND-enabling preclinical studies for TYRA-300 and plan to initiate IND-enabling preclinical studies for TYRA-200. If unexpected observations or toxicities are observed in these studies, or in IND-enabling studies for any of our other product candidates, this will delay and possibly prevent or limit clinical trials for TYRA-300, TYRA-200 or our other product candidates. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

For the foregoing reasons, we cannot be certain that our ongoing and planned preclinical studies and planned clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could impair the prospects for marketing approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

***Our discovery and preclinical development activities are focused on the development of targeted therapeutics for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs based on our SNÅP platform is novel and unproven and may never lead to approved products of commercial value.***

The discovery and development of targeted therapeutics for patients with genomically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. Although we believe, based on our preclinical work, that the genomic alterations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. In addition, even if our approach is successful in showing clinical benefit for acquired resistance mutation-driven cancers for our TYRA-300 and TYRA-200 inhibitor programs, we may never successfully identify additional oncogenic alterations for other receptor tyrosine kinases using our SNÅP platform, or succeed in identifying additional product candidates to address such alterations. Any product candidates we do discover and advance based on scientific approach may be later shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. Therefore, we do not know if our approach of discovering and developing product candidates to treat patients with genomically defined cancers will be successful, and if our approach is unsuccessful, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operation.

***Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.***

Before we can initiate clinical trials for our product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND application or similar regulatory filing required for regulatory acceptance before proceeding with clinical development. We are currently conducting IND-enabling studies for TYRA-300, and expect to submit an IND for TYRA-300 in mid-2022, followed by initiation of a Phase 1/2 clinical trial. We will also need to complete IND-enabling studies and submit INDs for TYRA-200 and our other development programs prior to initiating clinical development. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory filing, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our planned clinical trials for TYRA-300, TYRA-200, or any other product candidate, could significantly affect our product development timelines and development costs.

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or in vitro data to support the initiation or continuation of clinical trials;
- obtaining regulatory clearance to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- failure to reach an agreement with diagnostic companies for the use of liquid biopsy companion diagnostic tests in our clinical trials;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- identifying sufficient appropriately qualified investigators and other professionals to conduct the clinical trials;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate for use in clinical trials;
- patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including patients failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from the COVID-19 pandemic;
- patients choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials;
- patients experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in clinical trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components suspending or limiting manufacturing due to violations of current good manufacturing practice, or cGMP, or other applicable requirements, including infections or cross-contaminations of product candidates in the manufacturing process, or the facility being subject to other enforcement by the FDA or comparable foreign regulatory authorities that result in temporary or permanent manufacturing shut downs or product supply limitations;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials or being suspended or disqualified by the FDA or comparable foreign regulatory authorities, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or comparable foreign regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which our trials are being conducted, by a Data Safety Monitoring Board for our trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols and to make the appropriate required records, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or

adverse side effects, failure to demonstrate a benefit from using a clinical trial drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. These authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of a marketing application by the FDA or comparable foreign regulatory authorities and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

***Our proprietary SNÅP platform is innovative and unproven, and we do not know whether we will be able to develop any product candidates that are successful in clinical development or products of commercial value.***

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our proprietary SNÅP platform, which is designed to efficiently identify and selectively target vulnerabilities in the mutant proteins that commonly eliminate or reduce the effectiveness of standard-of-care therapies. Notwithstanding our preclinical study results for TYRA-300 and TYRA-200, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. TYRA-300 and TYRA-200 are in late preclinical development and we have not yet completed any clinical trials for any product candidate. Our SNÅP platform utilizes the rapid generation of precise molecular SNÅPshots to continually gain deeper insights into the structure of inhibitor binding sites and how commonly occurring resistance mutations lead to acquired drug resistance to existing therapies, which we believe aids in the prediction of amino acid residues most likely to cause resistance to specific existing therapies. This innovative process may never be successful in identifying additional product candidates with innovative structures that are able to inhibit the target while avoiding those specific residues. Further, because all of our product candidates and discovery programs are based on our SNÅP platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other development programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our innovative approach to compound identification. If we fail to stay at the forefront of technological innovation in utilizing our SNÅP platform, we may be unable to compete effectively.

***We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may not be able to complete clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment for our clinical trials may be affected by many factors, including:

- the size and nature of the patient population;
- the proximity of patients to clinical sites;
- the eligibility and exclusion criteria for the trial;

- the design of the clinical trial;
- the risk that enrolled patients will not complete a clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development.

We will be required to identify and enroll a sufficient number of patients for each of our clinical trials. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and commercialize our product candidates and achieve profitability. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing patients may prove costly.

The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. If patients are unwilling to participate in our trials for any reason, including the existence of concurrent clinical trials for similar patient populations or the availability of other therapies, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting clinical trials and obtaining marketing approval of our product candidates may be delayed. Additionally, because our initial planned clinical trials will be in patients with relapsed/refractory cancer, these patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

***Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.***

We have not evaluated any of our product candidates in human clinical trials. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. As is the case with biopharmaceuticals generally, and treatments for cancer and rare diseases in particular, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend or terminate future clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of

the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread if they receive marketing approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

Patients treated with our products, if approved, may experience previously unreported adverse reactions, and it is possible that the FDA or comparable foreign regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. If safety problems occur or are identified after our products, if any, are available for commercial sale and use, we may make the decision, or be required by regulatory authorities, to amend the labeling of our product candidates, recall our product candidates or even withdraw approval for an approved product.

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

- regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients; or
- sales of the product may decrease significantly or the product could become less competitive and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***We may not be able to submit INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

We may not be able to submit INDs for our existing and future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

***Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.***

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive marketing approval from the FDA. The process of obtaining marketing approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, marketing approval is never guaranteed. Neither we, nor any future collaborator, is permitted to market any of our product candidates in the United States until we receive marketing approval from the FDA.

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

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

- such authorities may disagree with the design or implementation of our, or our any of our potential future collaborators' clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we, or any of our potential future collaborators may be unable to demonstrate that a product candidate is safe and effective, and that product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- such authorities may require additional information, data, qualification, or validation of our manufacturing and testing processes as part of the chemistry, manufacturing, and controls information we submit as part of our application;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;

- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies;

- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or

- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

Any delays in the marketing approval of our product candidates may negatively impact our ability to successfully position the product candidate in the market or the product candidate may face additional competition from other products.

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

***We are required by the FDA (or comparable regulatory authority) to obtain approval or clearance of a companion diagnostic test in connection with approval of any of our product candidates. If we do not obtain or we face delays in obtaining approval of a diagnostic test, we may not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired.***

If we are required by the FDA or comparable foreign regulatory authorities to obtain approval or clearance of a companion diagnostic test in connection with marketing approval of any of our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. We will rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval or clearance for these companion diagnostics. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we and our future collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of these companion diagnostics, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval or clearance of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genomic alteration that the companion diagnostic was developed to detect. If the FDA or comparable foreign regulatory authorities require approval or clearance of a companion diagnostic for any of our product candidates, whether before or concurrently with marketing approval of the product candidate, we and/or our collaborators, may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or potential future collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on any companion diagnostic strategy we undertake. This guidance and future issuances from the FDA or comparable foreign regulatory authorities may impact our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon any partnered companion diagnostic development plans we undertake or we may not be able to compete effectively upon marketing approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the

companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval or clearance for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

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

Because we have limited financial and managerial resources, we focus on specific product candidates, development programs and specific indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable potential 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 product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***We may not be able to obtain or maintain orphan drug designations for any of our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Medicines Agency's, or EMA's, Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. We have not received orphan drug designation in the United States for any product candidate. We may seek orphan drug designation in the United States and the European Union for TYRA-300 for patients with muscle invasive bladder cancer, or MIBC, and other rare tumors susceptible to an FGFR3 therapy, and similar designations for TYRA-200 and our other product candidates in qualified patient populations. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will grant orphan designation for any indication for which we apply, or that we will be able to maintain such designation.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authorities can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior because it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose

market share regardless of orphan drug exclusivity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

***If we successfully develop our product candidates, we may seek Breakthrough Therapy designation or Fast Track designation by the FDA for one or more of our product candidates, but we may not receive such designation, and even if we do, such designation 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 may seek Breakthrough Therapy or Fast Track designation for some of our product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biologics that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Drugs or biologics designated as Breakthrough Therapies by the FDA may also be eligible for expedited review and approval. If a product candidate is intended for the treatment of a serious or life-threatening condition and clinical or preclinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we obtain Fast Track Designation for one or more of our product candidates, we may not experience a faster development process, review or approval compared to non-expedited FDA review procedures. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

Whether to grant Breakthrough Therapy or Fast Track Designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of either of these designations for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for either of these designations, the FDA may later decide that the product candidate no longer meet the conditions for qualification.

***We may in the future conduct clinical trials for certain of our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.***

We may conduct one or more of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. For trials that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCP and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such trials not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the trials, and therefore there is an additional potential risk that the FDA could determine that the trial design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. In addition, such foreign trials would be subject to the applicable local laws of the foreign regulatory and legal requirements where the trials are conducted. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. 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 changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline or preliminary data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

***Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.***

Where appropriate, we plan to seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug or biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor’s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug’s clinical benefit. If such post-approval studies fail to confirm the drug or biologic’s clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug or biologic.

We have not yet applied for accelerated approval by the FDA. Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors, we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval program, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to

commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. And on April 14, 2021, the FDA announced guidance regarding Remote Interactive Evaluations, and how they will be requested by the FDA and conducted for the duration of the COVID-19 public health emergency at any facility where pharmaceutical products, including biological products, are manufactured, processed, packed or held; facilities covered under the FDA's bioresearch monitoring program; and outsourcing facilities registered under FDCA section 503B. The FDA intends to use information from remote interactive evaluations to meet user-fee commitments and to update facilities information, when deemed appropriate based on risk and history of compliance with FDA regulations. Facilities can choose to decline the FDA's request to perform a remote facility evaluation; however, this may delay the agency's ability to evaluate the facility or product and make a regulatory decision. The FDA will not accept requests from applicants or facilities to perform a remote interactive evaluation, as decisions to offer a remote interactive evaluation will rest with the FDA, based on risk and compliance history.

Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through preclinical studies and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we have recently changed the delivery vehicle we use in our formulation for TYRA-300 from polyethylene glycol 400 to a cyclodextrin based vehicle. While we have observed positive results in a preclinical model using this new delivery vehicle, any further changes in formulation may result in effects and results that are different from those observed in our completed preclinical studies to date. Similarly, in the future we may introduce an alternative formulation of one or more of our product candidates during the course of our planned clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay initiation or completion of clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

**Risks Related to Our Reliance on Third Parties**

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

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We plan to rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA to the FDA or any comparable filing to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance, qualified personnel, and accurate and complete recordkeeping. If the FDA or comparable foreign regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us or the third-party manufacturers, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product candidates or any other future product candidates.

In addition, we do not have any long-term commitments or supply agreements with our third party manufacturers. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of our product candidates or such quantifies at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

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

Our product candidates and any products that receive marketing approval may compete with the product candidates and products of other companies for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Public health emergencies, such as that declared for COVID-19, might cause third-party manufacturers with whom we contract to prioritize the production of other products, possibly at the direction of the United States. or other government. This could lead to a delay in the manufacture of our product candidates or any products that receive marketing approval, and negatively impact the supply of such product candidates or products for clinical trials or commercialization.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods.

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

***Our reliance on third parties requires us to share our confidential information, which increases the possibility that confidential information will be misappropriated or disclosed.***

Because we currently plan to rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and confidential information and despite our efforts to protect our confidential information, a competitor’s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.***

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. We may have to relinquish valuable rights to our future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned or the sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control

decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

***We rely on third parties to conduct some of our preclinical studies and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain marketing approval for or commercialize our product candidates may be delayed.***

We are dependent on third parties to conduct some of our preclinical studies and expect to rely on such third parties for our clinical trials, including our planned Phase 1/2 clinical trial of TYRA-300. Specifically, we have used and relied on, or intend to use and rely on, medical institutions, clinical investigators, CROs, contract development and manufacturing organizations, and consultants to conduct some of our preclinical studies and to conduct planned clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these preclinical studies and clinical trials and subsequent collection and analysis of data. While we have and will have agreements governing the activities of our CROs, investigators and other third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA or comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, principal investigators, trial sites, and other third parties. If we or any of our CROs, trial sites or other third parties fail to comply with applicable GLP or GCP or other requirements, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may also serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management’s time and focus. In addition, there is a natural transition period when a new CRO, investigator or other third party contractor commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

**Risks Related to Commercialization of Our Product Candidates**

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

Following potential approval of any our product candidates, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export recordkeeping, and other activities relating to our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post- approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Later discovery of previously unknown problems with our products, including additional adverse events or 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 products, withdrawal of the product from the market or product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, civil money penalties, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

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

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

***The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.***

Our product candidates may not be commercially successful. Even if any of our product candidates receive marketing approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our current or potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to

educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

***We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.***

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives marketing approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

***The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.***

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Moreover, we are initially developing TYRA-300 for the treatment of MIBC, an indication with a small patient population. In order for products that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such products must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate with a smaller patient population that accounts for the smaller potential market size. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our

products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop, once approved. In addition, in the event that we or third parties develop companion diagnostic tests for use with our products, once approved, such companion diagnostic tests will require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement applicable to pharmaceutical or biological products will apply to companion diagnostics tests.

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

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

***We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.***

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products or product candidates competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In particular, there is intense competition in the precision oncology field. Our competitors include larger and better-funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling patients for clinical trials and in identifying and in-licensing new product candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect to face competition from existing products and products in development for each of our product candidates. There are three currently approved pan-FGFR inhibitors: Incyte Corporation's Pemazyre® (pemigatinib) and QED Therapeutics' Truseltiq® (infigratinib), approved in FGFR2 gene rearrangements in cholangiocarcinoma, and Janssen Biotech, Inc.'s Balversa® (erdafitinib), approved in specific FGFR3 and FGFR2 gene alterations. There are a number of other pan-FGFR programs in development for FGFR2 and FGFR3-specific populations, including, among others, Taiho Oncology, Inc.'s TAS-120 (futibatinib), Bayer Pharmaceutical's BAY 1163877 (Rogaratinib), as well as isoform specific FGFR inhibitors such as Relay Therapeutics, Inc.'s RLY-4008, Kinnate Biopharma Inc.'s KIN-3248 and Lilly's Loxo Oncology's recently announced isoform-selective FGFR3 inhibitor compound, LOXO-435 (LOX-24350). There are two approved RET inhibitors, Lilly's Loxo Oncology's Retevmo™ (selpercatinib) and Blueprint Medicines' Gavreto™ (pralsetinib), as well as programs in development such as Turning Point's TPX-0046 and Boston Pharmaceuticals' BOS172738. There are currently no approved FGFR4 inhibitors, but there are a number of FGFR4 programs in clinical development, including Blueprint Medicines' BLU-554 (fisogatinib), H3 Biomedicines' H3B-6527 and Novartis' FGF401.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain marketing approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered

and the extent to which patients accept relatively new routes of administration, the timing and scope of marketing approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products or technological approaches may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

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

The precise incidence and prevalence for all the conditions we aim to address with our product candidates 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 product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these indications. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates which receives marketing approval for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates 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. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive marketing approval from applicable regulatory authorities in foreign markets, and we may never receive such marketing approvals for any of our product candidates. To obtain separate marketing approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain marketing approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and 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 currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

**Risks Related to Our Business Operations and Industry**

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, marketing approval and commercialization activities relating to our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

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

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

***We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.***

Our success depends in part on our continued ability to attract, retain, manage and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the San Diego County area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that

will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

***We have recently substantially increased, and will need to continue to grow, the size and capabilities of our organization, and we may experience difficulties in managing this growth.***

We have substantially increased our organization from four employees as of December 31, 2019 to  full-time employees as of September 30, 2021, including 16 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need to continue to add significant additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining and motivating our current and additional employees;
- managing our internal development efforts effectively, including the preclinical, clinical, the FDA or comparable foreign regulatory authorities' review process for product candidates, while complying with any contractual obligations to contractors and other third parties;
- managing increasing operational and managerial complexity; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize TYRA-300 and any of our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***We are subject to various federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include, without limitation:

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order 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 Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics 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 Centers for Medicare & Medicaid Services, or CMS, information related to payments and 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 such healthcare professionals and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biopharmaceutical and biotechnology companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical and biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock or stock options as compensation for services provided to us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We, our future collaborators and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties and otherwise harm our business.

We are subject to laws and regulations governing the privacy and security of sensitive information, including confidential business and patient health information. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal data. Guidance on implementation and compliance practices are often updated or otherwise revised.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, HIPAA imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the U.S. Department of Health and Human Services, or HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a

breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Further, in November 2020, California voters approved the California Privacy Rights Act, or CPRA, through a ballot measure. The CPRA will amend the CCPA, giving California residents additional control over their personal information and imposing further obligations on businesses processing the personal information of California residents. The CPRA includes the creation of a privacy-specific enforcement agency, the first of its kind in any U.S. state, which will be responsible for enforcing the new law. The CPRA takes effect on January 1, 2023. More recently, Virginia adopted a generally applicable privacy law, and other states are considering similar steps.

These laws subject us to increased regulatory scrutiny, litigation, and overall risk. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject, if it is enacted. Without an overarching federal law driving privacy compliance in the United States, however, the risk is high of a patchwork of privacy legislation formed by individual state laws, similar to the patchwork created by differing state data breach notification obligations. Requirements to comply with varying state laws not only increase costs for compliance, but also create the potential for enforcement by individual state attorneys general.

In the European Union, in May 2018, a new privacy regime, the General Data Protection Regulation, or GDPR, took effect in the European Economic Area, the EEA. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. The GDPR introduced new requirements for the protection of personal data subject to GDPR and provides for substantial fines for non-compliance, including fines up to the greater of EUR 20 million or 4% of a company's annual global revenues.

The withdrawal of the UK from the EU further complicated European compliance obligations, as we must also comply with data privacy and security laws in effect in the UK that are substantially similar to the GDPR. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

***Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, was enacted in the United States. Among the provisions of the ACA of importance to our potential product candidates, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness

research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the healthcare reform measures of the Biden administration and other efforts, if any, to repeal and replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. Most recently, in March 2021, Congress enacted the American Rescue Plan Act of 2021, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100% of the average manufacturer price for a covered outpatient drug. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2031, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Although a number of these and other measures may require additional authorization to become effective, Congress and the current U.S. administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that the ACA, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

***We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.***

We and any of our third-party suppliers and potential future collaborators will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance

coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or marketing approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

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

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. 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 or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products, if approved;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

We currently do not hold product liability insurance coverage, but will need to obtain this insurance coverage prior to commencing clinical trials of our product candidates. We may need to increase our insurance coverage as we initiate additional clinical trials or if we commence commercialization of our product candidates, if ever. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we expect to obtain and maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will 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.

***Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter, including product liability insurance. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile workers' compensation, directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

***We and any of our potential future collaborators will be required to report to regulatory authorities if any of our product candidates or approved products in clinical trials cause or contribute to certain adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.***

The FDA or comparable foreign regulatory authorities would require that we and potential future collaborators report certain information about adverse medical events relating to any product that is approved or product candidate in clinical trials. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a comparable foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

***Our internal computer systems, or those of any of our CROs, other contractors or consultants or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development programs, harm our reputation, significant fines, penalties and liability and loss of customers or sales.***

The United States federal and various state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the collection, use, and dissemination of such data. In the ordinary course of business, we collect, store, transmit and otherwise process large amounts of data including, without limitation, proprietary business information and personal information. Despite the implementation of security measures, our internal technology systems (including infrastructure) and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, cybersecurity threats (such as denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks), unauthorized access or use, natural disasters, terrorism, war and telecommunication and electrical failures. Our systems are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper or accidental actions by employees, vendors and other third parties with otherwise legitimate access to our systems. Third parties may also attempt to fraudulently induce our employees and contractors into disclosing sensitive information such as usernames, passwords or other information, or otherwise compromise the security of our electronic systems, networks, and/ or physical facilities in order to gain access to our data.

Given the unpredictability of the timing, nature and scope of information technology disruptions, there can be no assurance that any security procedures and controls that we or our third-party partners and service providers have implemented will be sufficient to prevent cyber-attacks from occurring. The latency of a compromise is often measured in months, but could be years, and we may not be able to detect a compromise in a timely manner. New techniques may not be identified until they are launched against a target, and we may be unable to anticipate these techniques or detect an incident, assess its severity or impact, react or appropriately respond in a timely manner or implement adequate preventative measures, resulting in potential data loss or other damage to our information technology systems.

If a security breach were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as GDPR), it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Also, due to the COVID-19 pandemic, all of our employees are working remotely. As a result, we may have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement IT controls to reduce the risk of a cyber security or data security breach, there is no guarantee that these measures will be adequate to safeguard all systems, especially with an increased number of employees working remotely.

Any security breach or other incident, whether real or perceived, could impact our reputation, impact the integrity of our data, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any real or perceived disruption or security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

***Our business is subject to risks arising from COVID-19 and other epidemic diseases.***

The COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. A pandemic, including COVID-19, or other public health epidemic, poses the risk that we or our employees, contractors, including our CROs, suppliers, collaborators and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. In response, we have closed our executive offices with our administrative employees continuing their work remotely and limited the number of staff in our research and development laboratories. To date we have not experienced material disruptions in our business operations. However, while it is not possible at this time to estimate the impact that COVID-19 could have on our business in the future, particularly as we advance our product candidates to clinical development, the continued spread of COVID-19 and the measures taken by the governmental authorities, and any future epidemic disease outbreaks, could: disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research, preclinical studies and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities; impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including the risk that participants enrolled in our clinical trials will contract COVID-19 or other epidemic disease while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic and any future epidemic disease could also potentially affect the business of the FDA or comparable foreign regulatory authorities, which could result in delays in meetings related to planned clinical trials. The COVID-19 pandemic and mitigation measures have had and may continue to have, and any future epidemic disease outbreak may have, an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

***Our business could be affected by litigation, government investigations and enforcement actions.***

We operate in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, product seizure, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time consuming. An adverse outcome resulting from any such proceeding, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare or regulatory debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

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

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

***We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

***Changes in U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.***

On March 27, 2020, the CARES Act was signed into law to address the COVID-19 crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) net operating loss, or NOL, rules (as discussed below), (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Internal Revenue Code of 1986, as amended, or the Code.

The Tax Cuts and Jobs Act of 2017, or the Tax Act, also significantly changed the U.S. federal income taxation of U.S. corporations. We continue to work with our tax advisors and auditors to determine the full impact the Tax Act and the CARES Act will have on us. We urge our investors to consult with their legal and tax advisors with respect to both the Tax Act and the CARES Act and the potential tax consequences of investing in our common stock.

***Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with our initial public offering or other ownership changes.***

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). At December 31, 2020, we had federal and state NOL carryforwards of approximately $11.7 million and $3.7 million, respectively.

Under the Tax Act, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely. Under the CARES Act, NOL carryforwards arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. Because we had no taxable income in our tax year ended December 31, 2020, which was our third corporate tax year, we do not anticipate that such provision of the CARES Act will be relevant to us. The ability to use federal NOL carryforwards to offset taxable income, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, our NOL carryforwards are subject to review and possible adjustment by the IRS, and state tax authorities. Under Section 382 of the Code, our federal NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership of our company. An “ownership change” pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our initial public offering, or IPO, or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

**Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain patent protection for our product candidates and other proprietary technologies we develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and other proprietary technologies we may develop may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and other proprietary technologies we may develop as well as our ability to operate without infringing upon the proprietary rights of others. We seek to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to our product candidates and other proprietary technologies we may develop. If we are unable to obtain or maintain patent protection with respect to our product candidates and other proprietary technologies we may develop, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection against competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, CROs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of biopharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect our product candidates and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the claim coverage in a patent application can be significantly reduced before the patent is granted. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our product candidates, patents protecting the product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant and inter partes review, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

***We do not own or license any issued patents and substantive examination has not begun on any of our pending patent applications, which makes it is difficult to forecast the extent of any future patent rights.***

We cannot be certain that the claims in our U.S. pending patent applications or corresponding international patent applications, or future patent applications in certain foreign territories, will be considered patentable by the USPTO. Patent claims are subject to revision during prosecution and pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, which will likely be several years from now, and then only to the extent the issued claims cover the third party’s technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology. At present, we have only filed U.S. provisional patent applications and international patent applications under the Patent Cooperation Treaty, or the PCT. None of our patent applications have entered substantive examination by a patent office, which makes it impossible at this time to gauge which art will be cited by examiners or the extent of any rejections we may receive. For example, examiners at a patent office may uncover prior art of which we were not previously aware, and if this cited prior art encompasses our claimed inventions, it may restrict patentability or prevent allowance of any pending patent claims. Furthermore, the patent prosecution process is expensive, time-consuming, and often a multi-year process. We and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Therefore, we cannot be certain that we will own any issued patents or develop a patent portfolio, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in U.S. and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary 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, could put 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Since March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first

to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. 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. For example, the scope of patentable subject matter under 35 U.S.C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our ability to protect and enforce our intellectual property in the future.

***Issued patents relating to our product candidates and other proprietary technologies we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.***

If we initiated legal proceedings against a third party to enforce a patent relating to our product candidates and other proprietary technologies we may develop, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our product candidates and other proprietary technologies we may develop. 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 or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and other proprietary technologies we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

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

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

***If we do not obtain patent term extension for our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidate we may develop, one or more of patents issuing from our U.S. patent applications may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term, or PTE, of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate, or SPC. If we encounter delays in our development efforts, including any clinical trials, the period of time during which we could market any future product candidates under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to seeking patent protection for our product candidates and other proprietary technologies we may develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to our development programs, we consider trade secrets and know-how to be one of our important sources of intellectual property, including our extensive knowledge of crystallography structure-based drug design. Trade secrets and know-how can be difficult to protect. In particular, the trade secrets and know-how in connection with our development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, CROs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

We may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not be successful in obtaining necessary rights to any product candidate we may develop through acquisitions and in-licenses.***

We currently solely own intellectual property rights covering our product candidates. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our product candidates and other proprietary technologies we may develop. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.***

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biopharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators may prevent or delay the development and commercialization of our product candidates and other proprietary technologies we may develop.***

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biopharmaceutical and biotechnology industries, as well as administrative proceedings for challenging patents, including derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, as a result of the America Invests Act, procedures including inter partes review and post-grant review have been implemented. The America Invents Act adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our product candidates and in which we are developing other proprietary technologies. As the biopharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our product candidates and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents

owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our planned products. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. In this case, the holders of such patents may be able to block our ability to commercialize the infringing products or technologies unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, 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 and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidate or technologies, which could harm our business significantly. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop our product candidate and commercialize our product, if approved, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Engaging in litigation defending against third parties alleging infringement of patent and other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our product candidates.

***We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Third parties, such as a competitor, may infringe, misappropriate, or otherwise violate our future issued patents and other intellectual property rights. In a patent infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question or that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). In addition, our patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue any clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

***Intellectual property rights do not necessarily address all potential threats.***

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

- others may be able to make products that are similar to our product candidate or utilize similar technology but that are not covered by the claims of the patents that we may license or may own;
- we might not have been the first to make the inventions covered by our current or future patent applications;
- we might not have been the first to file patent applications covering our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future patent applications will not lead to issued patents;
- any patent issuing from our current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

***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.***

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary component and process rights. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. We plan to work with diagnostic companies to use liquid biopsy companion diagnostic tests to aid in identifying appropriate patients for the initial clinical trial. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive 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.

Additionally, we might sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that 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. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

***We, our collaborators and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties and otherwise harm our business.***

We may maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical studies, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal data. Guidance on implementation and compliance practices are often updated or otherwise revised.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, HIPAA imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the FTC failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

In the European Union, in May 2018, a new privacy regime, the GDPR, took effect in the EEA. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes new requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and

requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). 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. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

**Risks Related to Our Common Stock**

***Prior to our IPO, there was no public market for our common stock and an active, liquid and orderly market for our common stock may not develop or be sustained.***

Prior to our IPO, there was no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Select Market, or Nasdaq, and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active market is developed, it may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

***The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- results of our preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- marketing approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire or license additional product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;

- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- expiration of market stand-off or lock-up agreements;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

***Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly control or influence all matters submitted to stockholders for approval.***

Following completion of our IPO and based on our shares of common stock outstanding as of September 30, 2021, our executive officers, directors and greater than 5% stockholders, in the aggregate, owned approximately 57.4% of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly control or influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

In connection with our IPO, our directors and executive officers and holders of substantially all of our outstanding securities prior to the IPO entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of the Prospectus for the IPO, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of BofA Securities, Inc., Jefferies LLC and Cowen and Company, LLC. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. After the lock-up agreements expire, these shares of common stock will

be eligible for sale in the public market, except that shares held by our directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act. In addition, as of September 30, 2021, 2,586,313 shares of common stock that are subject to outstanding options under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. Any sales of these shares of our common stock, or if it is perceived that they will be sold, in the public market, could cause the trading price of our common stock to decline.

The holders of 26,228,089 shares of our outstanding common stock, or approximately 63.6% of our total outstanding common stock based on shares outstanding as of September 30, 2021, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. 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.

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five- year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide 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;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year.

**General Risk Factors**

***We incur significant 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 Exchange Act, which requires, among other things, that we file with 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 Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. 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.

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

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

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

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

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;

- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;

- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated 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.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud***.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

**Unregistered Sales of Equity Securities**

None.

**Use of Proceeds from Initial Public Offering**

On September 14, 2021, our registration statement on Form S-1 (File No. 333- 258970) was declared effective by the SEC for our IPO. At the closing of the offering on September 17, 2021, we sold 12,420,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,620,000 additional shares, at an initial public offering price of $16.00 per share and received gross proceeds of $198.7 million, which resulted in net proceeds to us of approximately $181.2 million, after deducting underwriting discounts and commissions of approximately $13.9 million and offering-related transaction costs of approximately $3.6 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. BofA Securities, Inc., Jefferies LLC, and Cowen and Company, LLC acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus.

**Issuer Repurchases of Equity Securities**

None.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed Herewith |
|---|---|---|---|---|---|
| | | Form | Date | Number | |
| 3.1 | Amended and Restated Certificate of Incorporation | 8-K | 9/17/21 | 3.1 | |
| 3.2 | Amended and Restated Bylaws | 8-K | 9/17/21 | 3.2 | |
| 4.1 | Specimen stock certificate evidencing the shares of common stock | S-1 | 8/20/21 | 4.1 | |
| 4.2 | Amended and Restated Investors' Rights Agreement, dated March 5, 2021, by and among the Registrant and certain of its stockholders | S-1/A | 9/9/21 | 4.2 | |
| 10.1# | Tyra Biosciences, Inc. 2021 Incentive Award Plan and form of stock option grant notice and stock option agreement thereunder | S-1/A | 9/9/21 | 10.2 | |
| 10.2# | Tyra Biosciences, Inc. 2021 Employee Stock Purchase Plan | S-1/A | 9/9/21 | 10.3 | |
| 10.3# | Non-Employee Director Compensation Program | S-1/A | 9/9/21 | 10.4 | |
| 10.4# | Second Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Todd Harris and the Registrant | S-1 | 8/20/21 | 10.12 | |
| 10.5# | Second Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Daniel Bensen and the Registrant | S-1 | 8/20/21 | 10.13 | |
| 10.6# | Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Esther van den Boom and the Registrant | S-1 | 8/20/21 | 10.14 | |
| 10.7# | Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Ronald Swanson and the Registrant | S-1 | 8/20/21 | 10.15 | |
| 10.8# | Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Hiroomi Tada and the Registrant | S-1 | 8/20/21 | 10.16 | |
| 10.9# | Amended and Restated Employment Agreement, dated August 18, 2021, by and between Robert Hudkins and the Registrant | S-1 | 8/20/21 | 10.17 | |
| 10.10# | Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Piyush Patel and the Registrant | S-1 | 8/20/21 | 10.18 | |
| 10.11# | Form of Indemnification Agreement for Directors and Officers | S-1 | 8/20/21 | 10.20 | |
| 31.1 | Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | X |
| 31.2 | Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | X |
| 32.1* | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | X |
| 32.2* | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | X |
| 101.INS | Inline XBRL Instance Document | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | | X |
| 101.CAL | Inline XBRL Taxonomy Calculation Linkbase Document | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | | | | X |
| 101.LAB | Inline XBRL Taxonomy Label Linkbase Document | | | | X |
| 101.PRE | Inline XBRL Presentation Linkbase Document | | | | X |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) | | | | X |

# Indicates management contract or compensatory plan.

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

**SIGNATURES**

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

TYRA BIOSCIENCES, INC.

Date: November 3, 2021 By: /s/ Todd Harris, Ph.D.

**Todd Harris, Ph.D.**
**President, Chief Executive Officer, and Director**
**(Principal Executive Officer)**

Date: November 3, 2021 By: /s/ Esther van den Boom

**Esther van den Boom**
**Chief Financial Officer**
**(Principal Financial and Accounting Officer)**

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Todd Harris, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2021

By: /s/ Todd Harris, Ph.D.

**Todd Harris, Ph.D.**
**President, Chief Executive Officer, and Director**

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Esther van den Boom, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2021

By: /s/ Esther van den Boom
**Esther van den Boom**
**Chief Financial Officer**

**Exhibit 32.1**

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

In connection with the Quarterly Report of Tyra Biosciences, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 3, 2021

By: /s/ Todd Harris, Ph.D.
**Todd Harris, Ph.D.**
**President, Chief Executive Officer, and Director**

**Exhibit 32.2**

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

In connection with the Quarterly Report of Tyra Biosciences, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 3, 2021

By: /s/ Esther van den Boom

**Esther van den Boom**
**Chief Financial Officer**