# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

## **FORM 10-Q**

(Mark One)

 $\mathbf{X}$ 

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

For the quarterly period ended June 30, 2023

OR

to

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

For the transition period from \_\_\_\_\_

Commission File Number: 001-39488

# Apexigen, Inc.

(Exact Name of Registrant as Specified in its Charter)

**Delaware** (State or other jurisdiction of incorporation or organization)

900 Industrial Road, Suite C San Carlos, CA

(Address of principal executive offices)

85-1260244 (I.R.S. Employer Identification No.)

> 94070 (Zip Code)

Registrant's telephone number, including area code: (650) 931-6236

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

| Title of each class  | Trading<br>Symbol(s) | Name of each exchange on which registered |
|--|----------------------|---|
| Common Stock, par value \$0.0001 per share                       | APGN                 | The Nasdaq Stock Market LLC               |
| Warrants, each whole warrant exercisable for one share of Common | APGNW                | The Nasdaq Stock Market LLC               |
| Stock at an exercise price of \$11.50 per share                  |                      |   |

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   | X | Smaller reporting company | X |
|                         |   | Emerging growth company   | X |

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 August 4, 2023, the registrant had 24,861,926 shares of common stock, \$0.0001 par value per share, outstanding.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing, and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements about:

- our expectations regarding the length of time that our existing capital resources will be sufficient to enable us to fund our planned operations, including our ability to continue as a going concern;
- our public securities' potential liquidity and trading;
- our ability to maintain the listing of our public securities on the Nasdaq Stock Market;
- our projected financial performance and market opportunity;
- estimates of our expenses, capital requirements, and need for additional financing;
- the anticipated benefits of cost-reduction efforts;
- our expectations regarding the anticipated timing and benefits of the contemplated merger transaction with Pyxis Oncology;
- the outcome of any legal proceedings that may be instituted against us related to the contemplated merger transaction with Pyxis Oncology;
- the efficacy of immuno-oncology therapeutics in the treatment of cancer;
- the timing and focus of our current and future clinical trials, and the reporting of data from those trials;
- the ability of our clinical trials to demonstrate safety and efficacy, and other positive results, of our product candidates;
- the anticipated beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- our estimates of the number of patients in the United States who suffer from the diseases we are targeting and the number of patients that will enroll in clinical trials;
- the timing or likelihood of regulatory filings and approvals for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to commercializing our product candidates, if approved, including which indications will be pursued;
- the development of competitors' product candidates;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- the impact of rising interest rates and geopolitical risks on our business and operations;
- the impact of our corporate restructuring to explore strategic alternatives, including the impacts of our reduction in the size of our workforce and adoption of a retention plan in connection with such restructuring;
- our ability to retain, manage and motivate members of our senior management team and other key personnel;
- our plans and ability to obtain, maintain, enforce, or protect intellectual property rights;
- our ability to establish and maintain relationships with, and our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; and

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the success of our licensing agreements and clinical development by our licensees.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this report and are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in this report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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, or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements. Item 1. Unaudited Condensed Consolidated Financial Statements.

## APEXIGEN, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands, except share and per share amounts)

|   |    | June 30,<br>2023     |    | December 31,<br>2022 |
|---|----|----------------------|----|----------------------|
| Assets  |    | (Unaudited)          |    |                      |
| Current assets:   |    |                      |    |                      |
| Cash and cash equivalents   | \$ | 9,369                | \$ | 14,802               |
| Short-term investments  | Ψ  | -                    | Ψ  | 1,997                |
| Prepaid expenses and other current assets   |    | 1,455                |    | 2,618                |
| Deferred financing costs, current   |    | 1,776                |    | 1,776                |
| Total current assets  |    | 12,600               |    | 21,193               |
| Property and equipment, net   |    | ,                    |    | 150                  |
| Right-of-use assets   |    | -                    |    | 100                  |
| Deferred financing costs, non-current   |    | 148                  |    | 1,036                |
| Other assets  |    | 335                  |    | 376                  |
| Total assets  | \$ | 13,083               | \$ | 22,855               |
| Liabilities and Stockholders' Equity  |    |                      |    |                      |
| Current liabilities:  |    |                      |    |                      |
| Accounts payable  | \$ | 3,381                | \$ | 5,343                |
| Accrued liabilities   |    | 5,362                |    | 5,359                |
| Deferred revenue  |    | 6,662                |    | 5,659                |
| Lease liabilities, current portion  |    | -                    |    | 106                  |
| Total current liabilities   |    | 15,405               |    | 16,467               |
| Derivative warrant liabilities  |    | -                    |    | 11                   |
| Total liabilities   |    | 15,405               |    | 16,478               |
| Commitment and contingencies (Note 9)   |    |                      |    |                      |
| Stockholders' (deficit) equity:   |    |                      |    |                      |
| Common stock, \$0.0001 par value; 1,000,000,000 shares authorized as of June 30, 2023 (unaudited) and December 31, 2022; 24,850,082 and 22,646,015 shares issued and outstanding as of June 30, 2023 (unaudited) and December 21, 2022, respectively. |    | 2                    |    | 2                    |
| (unaudited) and December 31, 2022, respectively   |    | 2                    |    | 192.169              |
| Additional paid-in capital<br>Accumulated deficit   |    | 186,569<br>(188,893) |    | 183,168<br>(176,793) |
|   |    |                      |    | <u> </u>             |
| Total stockholders' (deficit) equity  | ¢  | (2,322)              | ¢  | 6,377                |
| Total liabilities and stockholders' equity  | \$ | 13,083               | \$ | 22,855               |

See accompanying notes to unaudited condensed consolidated financial statements.

## APEXIGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (In thousands, except share and per share amounts) (Unaudited)

|  | Three Months Ended<br>June 30, |            |      | Six Months Ended<br>June 30, |    |            |    |            |
|--|--------------------------------|------------|------|------------------------------|----|------------|----|------------|
|  | 2023 2022                      |            | 2023 |                              |    | 2022       |    |            |
| Operating expenses:  |                                |            |      |                              |    |            |    |            |
| Research and development   | \$                             | 1,753      | \$   | 6,005                        | \$ | 4,689      | \$ | 13,113     |
| General and administrative   |                                | 4,405      |      | 2,139                        |    | 7,684      |    | 4,124      |
| Total operating expenses   |                                | 6,158      | _    | 8,144                        |    | 12,373     |    | 17,237     |
| Loss from operations   |                                | (6,158)    |      | (8,144)                      |    | (12,373)   |    | (17,237)   |
| Other income, net  |                                | 111        |      | 40                           |    | 273        |    | 91         |
| Net loss   | \$                             | (6,047)    | \$   | (8,104)                      | \$ | (12,100)   | \$ | (17,146)   |
| Net loss per share, basic and diluted  | \$                             | (0.24)     | \$   | (0.45)                       | \$ | (0.50)     | \$ | (0.95)     |
| Weighted-average common shares used to compute net loss per share, basic and diluted |                                | 24,725,768 |      | 18,090,770                   |    | 24,442,900 |    | 18,087,777 |
| Comprehensive Loss:  |                                |            |      |                              |    |            |    |            |
| Net loss   | \$                             | (6,047)    | \$   | (8,104)                      | \$ | (12,100)   | \$ | (17,146)   |
| Other comprehensive loss   |                                |            |      |                              |    |            |    |            |
| Unrealized gain on marketable securities   |                                | -          |      | (15)                         |    | -          |    | (13)       |
| Comprehensive loss   | \$                             | (6,047)    | \$   | (8,119)                      | \$ | (12,100)   | \$ | (17,159)   |

See accompanying notes to unaudited condensed consolidated financial statements.

## APEXIGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY (In thousands, except share amounts) (Unaudited)

|                                   | Three Months Ended June 30, 2023 |    |         |                                     |         |    |                                       |       |          |                     |               |
|-----------------------------------|----------------------------------|----|---------|-------------------------------------|---------|----|---------------------------------------|-------|----------|---------------------|---------------|
|                                   | Com<br>Sto                       |    |         | Additional<br>_ Paid-In Accumulated |         |    | Accumulated<br>Other<br>Comprehensive |       |          | Total<br>ckholders' |               |
|                                   | Shares                           |    | Amounts |                                     | Capital |    | Deficit                               | Incom | e (Loss) | Equi                | ity (Deficit) |
| Balance at April 1, 2023          | 24,652,546                       | \$ | 2       | \$                                  | 185,957 | \$ | (182,846)                             | \$    | -        | \$                  | 3,113         |
| Vesting of restricted stock units | 180,536                          |    | -       |                                     | 241     |    | -                                     |       | -        |                     | 241           |
| Issuance of common stock under    |                                  |    |         |                                     |         |    |                                       |       |          |                     |               |
| employee stock plan               | 17,000                           |    | -       |                                     | 5       |    | -                                     |       | -        |                     | 5             |
| Reclassification of private       |                                  |    |         |                                     |         |    |                                       |       |          |                     |               |
| warrants                          | -                                |    | -       |                                     | 13      |    | -                                     |       | -        |                     | 13            |
| Stock-based compensation          | -                                |    | -       |                                     | 353     |    | -                                     |       | -        |                     | 353           |
| Net loss                          | -                                |    | -       |                                     | -       |    | (6,047)                               |       | -        |                     | (6,047)       |
| Balance at June 30, 2023          | 24,850,082                       | \$ | 2       | \$                                  | 186,569 | \$ | (188,893)                             | \$    | -        | \$                  | (2,322)       |

|                                   |                      |    |           |    | Six Months Ende       | ed June     | 30, 2023  |  |       |    |                     |
|-----------------------------------|----------------------|----|-----------|----|-----------------------|-------------|-----------|--|-------|----|---------------------|
|                                   | Com<br>Sto           |    | A         |    | Additional<br>Paid-In | Accumulated |           | Accumulated<br>Other<br>Comprehensive<br>Income (Loss) |       |    | Total<br>skholders' |
| Dalance at January 1, 2022        | Shares<br>22,646,015 | \$ | Amounts 2 | \$ | Capital               | ¢           | Deficit   | \$   | LUSS) | ¢  | ty (Deficit)        |
| Balance at January 1, 2023        | 22,040,015           | Ф  | 2         | Ф  | 183,168               | Э           | (176,793) | Ф  | -     | \$ | 6,377               |
| Private offering, net of          |                      |    |           |    |                       |             |           |  |       |    |                     |
| transaction costs of \$659        | 1,995,708            |    | -         |    | 2,132                 |             | -         |  | -     |    | 2,132               |
| Vesting of restricted stock units | 191,359              |    | -         |    | 411                   |             | -         |  | -     |    | 411                 |
| Issuance of common stock under    |                      |    |           |    |                       |             |           |  |       |    |                     |
| employee stock plan               | 17,000               |    | -         |    | 5                     |             |           |  |       |    | 5                   |
| Reclassification of private       |                      |    |           |    |                       |             |           |  |       |    |                     |
| warrants                          | -                    |    | -         |    | 13                    |             | -         |  | -     |    | 13                  |
| Stock-based compensation          | -                    |    | -         |    | 840                   |             | -         |  | -     |    | 840                 |
| Net loss                          | -                    |    | -         |    | -                     |             | (12,100)  |  | -     |    | (12,100)            |
| Balance at June 30, 2023          | 24,850,082           | \$ | 2         | \$ | 186,569               | \$          | (188,893) | \$   | -     | \$ | (2,322)             |

See accompanying notes to unaudited condensed consolidated financial statements.

|  |                         |            |                | Three Months | Ended June 30, 2022   | !            |                                       |                        |
|--|-------------------------|------------|----------------|--------------|-----------------------|--------------|---------------------------------------|------------------------|
|  | Converti<br>Preferred S |            | Commo<br>Stock |              | Additional<br>Paid-In | Accumulated  | Accumulated<br>Other<br>Comprehensive | Total<br>Stockholders' |
|  | Shares                  | Amounts    | Shares         | Amounts      | Capital               | Deficit      | Loss                                  | Equity (Deficit)       |
| Balance at April 1, 2022, as previously reported | 145,130,628             | \$ 158,707 | 31,395,489     | \$ 31        | \$ 8,462              | \$ (153,766) | \$ (2)                                | \$ (145,275)           |
| Retroactive application of recapitalization      | (145,130,628)           | (158,707)  | (13,310,621)   | (29)         | 158,736               |              |                                       | 158,707                |
| Balance at April 1, 2022, as adjusted            | -                       | -          | 18,084,868     | 2            | 167,198               | (153,766)    | (2)                                   | 13,432                 |
| Exercise of stock options                        | -                       | -          | 6,760          | -            | 23                    | -            | -                                     | 23                     |
| Stock-based compensation                         | -                       | -          | -              | -            | 368                   | -            | -                                     | 368                    |
| Net loss   | -                       | -          | -              | -            | -                     | (8,104)      | -                                     | (8,104)                |
| Other comprehensive loss                         | -                       | -          | -              | -            | -                     | -            | (15)                                  | (15)                   |
| Balance at June 30, 2022                         |                         | \$ -       | 18,091,628     | \$2          | \$ 167,589            | \$ (161,870) | \$ (17)                               | \$ 5,704               |

|  |                                   |            |                          | Six Months l | Ended June 30, 2022              |                        |   |  |
|--|-----------------------------------|------------|--------------------------|--------------|----------------------------------|------------------------|---|--|
|  | Converti<br>Preferred S<br>Shares |            | Commo<br>Stock<br>Shares |              | Additional<br>Paid-In<br>Capital | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Loss | Total<br>Stockholders'<br>Equity (Deficit) |
| Palance et January 1, 2022                         | 51141 €5                          | Amounts    | Shares                   | Amounts      | Capital                          | Dencu                  | L055  | Equity (Dencit)                            |
| Balance at January 1, 2022, as previously reported | 145,130,628                       | \$ 158,707 | 31,070,665               | \$ 31        | \$ 7,991                         | \$ (144,724)           | \$ (4)  | \$ (136,706)                               |
| Retroactive application of recapitalization        | (145,130,628)                     | (158,707)  | (13,019,073)             | (29)         | 158,736                          | -                      | -   | 158,707                                    |
| Balance at January 1, 2022, as adjusted            |                                   | _          | 18,051,592               | 2            | 166,727                          | (144,724)              | (4)   | 22,001                                     |
| Exercise of stock options                          | -                                 | -          | 40,036                   | -            | 73                               | -                      | -   | 73   |
| Stock-based compensation                           | -                                 | -          | -                        | -            | 789                              | -                      | -   | 789  |
| Net loss   | -                                 | -          | -                        | -            | -                                | (17,146)               | -   | (17,146)                                   |
| Other comprehensive loss                           | -                                 | -          | -                        | -            | -                                | -                      | (13)  | (13)                                       |
| Balance at June 30, 2022                           |                                   | \$ -       | 18,091,628               | \$2          | \$ 167,589                       | \$ (161,870)           | <u>\$ (17</u> )                               | \$ 5,704                                   |

See accompanying notes to unaudited condensed consolidated financial statements.

## APEXIGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (In thousands) (Unaudited)

|   | Six Months Ended June 30, |          |    |          |  |
|---|---------------------------|----------|----|----------|--|
|   |                           | 2023     |    | 2022     |  |
| CASH FLOWS FROM OPERATING ACTIVITIES:                                       |                           |          |    |          |  |
| Net loss  | \$                        | (12,100) | \$ | (17,146) |  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                           |          |    |          |  |
| Depreciation  |                           | 17       |    | 55       |  |
| Stock-based compensation  |                           | 840      |    | 789      |  |
| Expense from restricted stock units   |                           | 411      |    | -        |  |
| Accretion of discount and amortization of premiums on marketable securities |                           | (3)      |    | 7        |  |
| Amortization of deferred financing costs                                    |                           | 888      |    | -        |  |
| Change in fair value of derivative warrant liabilities                      |                           | 2        |    | -        |  |
| Non-cash lease expense  |                           | 100      |    | 200      |  |
| Gain on disposals   |                           | (16)     |    | -        |  |
| Changes in current assets and liabilities:                                  |                           |          |    |          |  |
| Prepaid expenses and other current assets                                   |                           | 1,182    |    | 82       |  |
| Other assets  |                           | 41       |    | (104)    |  |
| Accounts payable  |                           | (2,005)  |    | 2,058    |  |
| Accrued expenses  |                           | (17)     |    | (865)    |  |
| Deferred revenue  |                           | 1,003    |    | 991      |  |
| Lease liabilities   |                           | (106)    |    | (209)    |  |
| Net cash used in operating activities                                       |                           | (9,763)  |    | (14,142) |  |
| CASH FLOWS FROM INVESTING ACTIVITIES:                                       |                           |          |    |          |  |
| Purchases of property and equipment   |                           | -        |    | (43)     |  |
| Sales of property and equipment   |                           | 150      |    | -        |  |
| Purchases of marketable securities  |                           | -        |    | (14,985) |  |
| Sales of marketable securities  |                           | 2,000    |    | 17,947   |  |
| Net cash provided by investing activities                                   |                           | 2,150    |    | 2,919    |  |
| CASH FLOWS FROM FINANCING ACTIVITIES:                                       |                           |          |    |          |  |
| Proceeds from private offering  |                           | 2,791    |    | -        |  |
| Payments of transaction costs   |                           | (616)    |    | (649)    |  |
| Proceeds from issuances of common stock under equity stock purchase plan    |                           | 5        |    | -        |  |
| Proceeds from exercise of stock options                                     |                           | -        |    | 73       |  |
| Net cash provided by (used in) financing activities                         |                           | 2,180    |    | (576)    |  |
| Net decrease in cash and cash equivalents                                   |                           | (5,433)  |    | (11,799) |  |
| Cash and cash equivalents, beginning of period                              |                           | 14,802   |    | 23,443   |  |
| Cash and cash equivalents, end of period                                    | \$                        | 9,369    | \$ | 11,644   |  |
| Supplemental disclosure of non-cash investing and financing activities:     |                           |          |    |          |  |
| Transaction costs in accounts payable and accrued liabilities at period end | \$                        | 43       | \$ | 1,582    |  |
| Reclassification of private warrants  | \$                        | 13       | \$ | -        |  |
| · ·   |                           |          |    |          |  |

See accompanying notes to unaudited condensed consolidated financial statements.

## APEXIGEN, INC. NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Description of the Business

#### **Description of Business**

Apexigen, Inc. ("Apexigen" or "we") is a clinical-stage biopharmaceutical company focused on discovering and developing antibody therapeutics for oncology, with an emphasis on new immuno-oncology agents designed to harness the patient's immune system to combat and eradicate cancer. Our lead product candidates are sotigalimab ("sotiga" or "APX005M"), which is a CD40 agonist antibody, and APX601, which is a TNFR2 antagonist antibody. We also have out-license arrangements for a number of programs. Since inception, we have devoted substantially all of our resources to performing research, development, and manufacturing activities in support of our product candidates. In October 2019, the first of our out-licensed product candidates was approved for commercial product sale. Apexigen is headquartered in San Carlos, California.

In March 2022, Brookline Capital Acquisition Corp. ("BCAC") and Apexigen America, Inc., which was then known as Apexigen, Inc. ("Legacy Apexigen"), entered into a business combination agreement ("Brookline Business Combination Agreement") pursuant to which BCAC and Legacy Apexigen agreed to combine, with Legacy Apexigen's equityholders owning a majority of the equity in the combined public company. The transactions contemplated under the Brookline Business Combination Agreement (the "Brookline Merger") closed in July 2022. At that time, a subsidiary of BCAC merged with and into Legacy Apexigen with Legacy Apexigen surviving the merger as a wholly owned subsidiary of BCAC. Additionally, BCAC changed its name to Apexigen, Inc. and Legacy Apexigen changed its name to Apexigen America, Inc.

Legacy Apexigen was incorporated in Delaware in 2010, the year Legacy Apexigen was spun-out of Epitomics, Inc. ("Epitomics"), which was a California-based biotechnology company that was acquired by Abcam plc in 2012. Legacy Apexigen was spun-out of Epitomics to focus on the discovery, development, and commercialization of humanized monoclonal antibody therapeutics.

#### Liquidity, Capital Resources, and Recent Developments

On February 27, 2023, we announced that we were implementing a corporate restructuring to extend our cash runway as we reviewed and explored strategic alternatives. As part of the restructuring, which was approved by our board of directors on February 23, 2023, we announced plans to reduce the size of our workforce by 55%, impacting up to 11 of our 20 employee positions. We eliminated nine employee positions as of June 30, 2023 and do not expect to eliminate any additional positions prior to the completion of the merger with Pyxis Oncology, Inc. As a result of the restructuring, we incurred severance costs of \$0.1 million and \$0.4 million during the three and six months ended June 30, 2023, respectively.

On April 11, 2023, we received a written notice from the Listing Qualifications Staff of the Nasdaq Stock Market ("Nasdaq") notifying the Company that it has not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5450(a)(1) for a period of 30 consecutive business days (the "Notice"). This Notice has no immediate effect on the listing of our stock on the Nasdaq Capital Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a compliance period of 180 calendar days from the date of the Notice to regain compliance with the minimum closing bid price requirement. If we do not regain compliance during the compliance period, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we must meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market (with the exception of the minimum bid price requirement) and notify Nasdaq of our intent to cure the deficiency by effecting a reverse stock split if necessary. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, our stock will be subject to delisting.

We can achieve compliance with the minimum bid price requirement if, during either compliance period, the closing bid price per share of our stock is at least \$1.00 for a minimum of ten consecutive business days.

We intend to monitor the closing bid price of our stock and assess potential actions to regain compliance, but there can be no assurance that we will regain compliance with the minimum bid price requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

On May 23, 2023, we entered into an Agreement and Plan of Merger (the "Pyxis Merger Agreement") with Pyxis Oncology, Inc. ("Pyxis Oncology") and Ascent Merger Sub Corp., a wholly owned subsidiary of Pyxis Oncology ("Merger Sub"), pursuant to which Merger Sub will merge with and into Apexigen (the "Pyxis Merger"), with Apexigen surviving such merger as a wholly owned

subsidiary of Pyxis Oncology. The Pyxis Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. On June 30, 2023, we filed a definitive merger proxy statement announcing a special meeting of Apexigen stockholders to be held virtually on August 22, 2023. Holders of our common stock as of the close of business on June 28, 2023 (the "Record Date") are entitled to vote at the special meeting. The completion of the Pyxis Merger is subject to the satisfaction or waiver of certain closing conditions, including the approval of the adoption of the Pyxis Merger Agreement by a majority of our outstanding shares of common stock as of the Record Date. At the closing of the Pyxis Merger, each outstanding share of our common stock will automatically convert into the right to receive 0.1725 (the "Exchange Ratio") shares of common stock of Pyxis Oncology.

As of June 30, 2023, we had approximately \$9.4 million of cash and cash equivalents, and expect to fund our operations into the fourth quarter of 2023 based on current operations assuming no additional proceeds from our equity line agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") or any other potential financing or business development transactions. We have incurred substantial losses and negative cash flows from operations since inception and had an accumulated deficit of \$188.9 million as of June 30, 2023. Since inception through June 30, 2023, we have funded operations primarily through the issuance of equity, proceeds from collaborative research and development agreements, and borrowings under a debt arrangement. Due to our significant research, development, and manufacturing expenditures, we have generated operating losses in all periods presented. We expect to incur substantial additional losses in the future as we advance and expand our research and development activities and prepare to pursue the potential regulatory approval and commercialization of our product candidates. Based on our research and development activities and plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate the business effectively, which raises substantial doubt as to our ability to continue as a going concern.

We may seek additional funds through the sale and issuance of shares of our common stock in private or public offerings, other equity or debt financings, collaborations, or partnerships with third parties, or other transactions to monetize assets, including our right to receive milestone payments and royalties under our out-license arrangements. We cannot assure that we will succeed in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or preclinical studies or research and development programs. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenditures associated with our current and planned research, development, and manufacturing activities.

To the extent that we raise additional capital through strategic alliances, licensing arrangements or other monetization transactions with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of the then-existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting the ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

## 2. Summary of Significant Accounting Policies

#### **Unaudited Interim Financial Information**

The unaudited interim consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"), and in our opinion, include all adjustments of a normal recurring nature necessary for fair financial statement presentation. Interim results are not necessarily indicative of the results to be expected for the full year ending December 31, 2023. We have made estimates and assumptions that affect the amounts reported and disclosed in the unaudited interim consolidated financial statements and the accompanying notes. Actual results could differ materially from these estimates.

These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2022 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

As a result of the merger with BCAC in July 2022, we have retrospectively applied the effect of our 1:0.102448 reverse stock split to all shares outstanding, earnings per share, and equity plan amounts for all periods presented.

#### **Principles of Consolidation**

The unaudited condensed consolidated financial statements include the accounts of Apexigen and its wholly owned subsidiary. All significant intercompany transactions and balances have been eliminated in consolidation.



## **Emerging Growth Company**

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934 (the "Exchange Act") are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company, which is neither an emerging growth company nor an emerging growth company nor an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

#### Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts expensed during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to accruals for research and development costs, stock-based compensation, and uncertain tax positions. We adjust such estimates and assumptions when facts and circumstances dictate. Changes in those estimates resulting from continuing changes in the economic environment will be reflected in the consolidated financial statements in future periods. As future events and their effects cannot be determined with precision, actual results could materially differ from those estimates and assumptions.

#### Segment Reporting

We have one operating segment, which is the business of researching, developing and commercializing antibody therapeutics for oncology. Our chief operating decision maker, our Chief Executive Officer, manages our operations on an aggregated basis for the purposes of allocating resources and evaluating financial performance.

#### Cash and Cash Equivalents

We consider all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds. The carrying amount of cash equivalents approximates their fair value.

#### Short-Term Investments

Short-term investments consist of U.S. treasury securities with original maturities of greater than three months from the date of purchase but less than one year from the balance sheet date. Such investments are considered available-for-sale and reported at fair value with unrealized gains and losses included as a component of stockholders' equity. The amortized cost of the securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included as other income, net in the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in fair value determined to be other-than-temporary, if any, on investments are included in other income, net. We determine the cost of securities sold using the specific identification method.

#### Fair Value Measurements

We apply fair value accounting to all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis. The carrying amount of our financial assets and liabilities, including accounts payable and accrued expenses, approximate their fair values due to their short-term maturities.



#### **Concentrations of Credit and Other Risks**

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash and cash equivalents on deposit with financial institutions, the balance of which frequently exceed federally insured limits. On March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed Federal Deposit Insurance Corporation as receiver. If any of the financial institutions with whom we do business were to be placed into receivership, we may be unable to access to the cash we have on deposit with such institutions. If we are unable to access our cash and cash equivalents as needed, our financial position and ability to operate our business could be adversely affected. We limit our credit risk associated with cash and cash equivalents by placing them with financial institutions we believe are of high quality. We have not experienced any losses on our deposits of cash. As of June 30, 2023, we had no off-balance sheet concentrations of credit risk.

We are subject to a number of risks similar to other early-stage biopharmaceutical companies, including the need to obtain adequate additional funding, possible failure of clinical trials, the need to obtain marketing approval for our product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of our products, and protection of proprietary technology. If we do not successfully develop, obtain regulatory approval for, commercialize or partner our product candidates, we will be unable to generate revenue from product sales or achieve profitability.

#### Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets. The estimated useful life of laboratory equipment, furniture and fixtures, office equipment, and software ranges from two to five years. We expense maintenance, repair and calibration costs as incurred.

#### Impairment of Long-Lived Assets

Our long-lived assets are comprised principally of our property and equipment and right-of-use lease assets. We periodically evaluate our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets or group of assets may not be fully recoverable. We deem a long-lived asset impaired when the undiscounted future cash flows expected to be generated by the asset or group of assets is less than the carrying amount of the assets. If there is an impairment, we would reduce the carrying amount of the assets through an impairment charge, to their estimated fair values based on a discounted cash flow approach or, when available and appropriate, to comparable market values. We recorded no impairment of long-lived assets during the three and six months ended June 30, 2023 and 2022.

#### **Deferred Financing Costs**

Deferred financing costs consist of direct costs and commitment fees directly attributable to the commencement of the equity line agreement with Lincoln Park upon the closing of the merger with BCAC in July 2022. We capitalize deferred financing costs and amortize these costs over the 24 months of the equity line agreement. As of June 30, 2023, deferred financing costs totaled \$1.9 million. Amortization expense for deferred financing costs was \$0.4 million and \$0.8 million for the three and six months ended June 30, 2023.

#### **Revenue Recognition**

Under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, we recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consolidated balance sheets to which we expect to be entitled in exchange for those goods or services. We have not commenced sales of our drug candidates and did not have a product approved for marketing as of June 30, 2023.

We may also earn contingent fees, including milestone payments based on counterparty performance and royalties on sales, from collaborations and other out-license arrangements. We will recognize milestone payments as revenue once the underlying events are probable of being met and there is not a significant risk of reversal. We will recognize sales-based royalties as revenue when the underlying sales occur. In October 2019, Novartis' Beovu<sup>®</sup> product, which is covered by one of our out-license agreements, was approved for commercial product sale. Under this agreement, Novartis is obligated to pay us a very low single-digit royalty on net sales of the Beovu product. However, Novartis has disputed its obligation to pay us royalties on Beovu sales under this agreement. As a result, we have determined that any sales-based Beovu product royalty revenue that we may earn under this agreement is currently fully constrained. We have recorded the royalty proceeds as deferred revenue in the consolidated balance sheets. As of June 30, 2023 and December 31, 2022, deferred revenue totaled \$6.7 million and \$5.7 million, respectively.

#### Lease

We determine if an arrangement is a lease at inception and if so, we determine whether the lease qualifies as an operating or a finance lease. We previously leased our principal facility under a non-cancelable operating lease agreement with a lease term, which ended in March 2023. We currently lease our facility under a six-month lease that commenced in March 2023. We recognize the monthly rent of \$2,000 as rent expense and include it in operating expenses in the consolidated statements of operations and comprehensive income. As of June 30, 2023 and December 31, 2022, the right-of-use assets were zero and \$0.1 million, respectively, and lease liabilities were zero and \$0.1 million for the six months ended June 30, 2023 and 2022, respectively, and \$0.1 million and \$0.2 million for the six months ended June 30, 2023 and 2022, respectively.

#### **Research and Development Expenses**

Research and development costs are expensed as incurred. Research and development expenses are primarily for the development of sotiga, our lead product candidate, as well as APX601 and other preclinical product candidates. Research and development costs consist primarily of external costs related to clinical development, contract manufacturing, preclinical development and discovery as well as personnel costs and allocated overhead, such as rent, equipment, depreciation, and utilities. Personnel costs consist of salaries, employee benefits and stock-based compensation.

We estimate external research and development expenses based on the services performed, pursuant to contracts with commercial and academic institutions that conduct and manage research and development services on our behalf. We record the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the consolidated balance sheets. These costs are a component of our research and development expenses. We accrue these costs based on factors such as the number of patient visits, the number of active patients, the number of patients enrolled, estimates of the work completed and other measures in accordance with agreements established with our third-party service providers under the service agreements. As actual costs become known, we adjust our accrued liabilities. We have not experienced any significant differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in significant changes to our accruals could significantly affect our results of operations.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and then expensed as the related goods are delivered or the services are performed. We evaluate such payments for current or long-term classification based on when they will be realized.

#### **Transaction Costs**

Transaction costs consist of direct legal, accounting, filing and other fees and costs directly attributable to our exploration of strategic alternatives. We expense transaction costs in the period in which the costs are incurred and the services are received. Transaction costs were \$1.5 million and \$1.7 million for the three and six months ended June 30, 2023, respectively, and they were included as general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

#### **Common Stock Warrant**

We record at fair value freestanding puttable or redeemable warrants, or warrants which are not considered to be indexed to our stock and include this amount in accrued expenses on our consolidated balance sheets as of December 31, 2021. On the closing date of the merger with BCAC in July 2022, the preferred stock warrant that was outstanding immediately before closing became a common stock warrant. We adjusted the carrying value of such warrant to its estimated fair value at the closing date of the merger with BCAC based upon the value of our common stock warrant and reclassified estimated fair value at the closing date of the merger with BCAC from accrued expenses to additional paid-in capital on the closing date of the merger with BCAC. This common stock warrant of 4,321 shares is outstanding as of June 30, 2023.

#### **Public Warrants**

The public warrants, issued in connection with the BCAC's initial public offering prior to the merger between Apexigen and BCAC, and the warrants issued in private offering transactions completed in July 2022 and January 2023, are classified as equity (see Note 7).

#### **Derivative Warrant Liabilities**



We account for the private placement warrants (see Note 7) issued in connection with the initial public offering as derivative warrant liabilities in accordance with FASB ASC Topic 815, "*Derivative and Hedging*". Accordingly, we recognize the private placement warrants as liabilities at fair value and adjust the instruments to fair value at each reporting period. The liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized and included as other income, net in the condensed consolidated statements of operations and comprehensive loss. We measured the fair value of the private placement warrants using a Black-Scholes option-pricing model. The determination of the fair value of the warrant liabilities may be subject to change as more current information becomes available and accordingly the actual results could differ significantly.

As of June 30, 2023, the private placement warrants had been transferred from the initial purchaser to individuals. After the transfer, the terms of the private placement warrants became identical to the public warrants. The private placement warrants were re-measured and reclassified as equity. As of June 30, 2023 and December 31, 2022, deferred warrant liabilities were zero and approximately \$11,000, respectively. Change in fair value of derivative warrant liabilities was not significant for the three and six months ended June 30, 2023.

## Stock-Based Compensation

We measure all equity awards granted to employees and non-employees based on the estimated grant date fair value. For awards subject to servicebased vesting conditions, we recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting term. For awards subject to performance-based vesting conditions, we recognize stock-based compensation expense using the accelerated attribution method when it is probable that the performance condition will be achieved. We recognize forfeitures as they occur.

We use the Black-Scholes option-pricing model to estimate the fair value of equity awards and recognize expense using the straight-line attribution approach. The Black-Scholes option-pricing model requires assumptions to be made related to the expected term of the awards, expected stock priced volatility, risk-free rate for a period that approximates the expected term of the awards and the expected dividend yield.

#### **Income Taxes**

We account for income taxes under the asset and liability method. Under this method, we recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. We measure deferred tax assets and liabilities using enacted tax rates applied to taxable income in the years in which we expect to realize those temporary differences. We recognize the effect on deferred tax assets and liabilities of a change in tax rates as income or loss in the period that includes the enactment date. We establish a valuation allowance, when necessary, to reduce deferred tax assets to the amount we expect to realize. We recognize the financial statement effects of uncertain tax positions when it is more-likely-than-not, based on the technical merits of the position, that it will be sustained upon examination. We include interest and penalties related to unrecognized tax benefits within the provision of income tax. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

#### **Comprehensive Loss**

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss, primarily unrealized gains or losses on our marketable securities.

#### Net Loss per Share

We calculate basic net loss per share by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for each period presented, since the effects of potentially dilutive securities are antidilutive given our net loss.

#### **Major Vendors**

We had one major vendor that accounted for approximately 18.2% and 36.1% of the research and development expenses for the three months ended June 30, 2023 and 2022, respectively and approximately 16.2% and 39.4% of the research and development expenses for the six months ended June 30, 2023 and 2022, respectively. The same vendor also accounted for approximately 8.0% and 24.8% of the total accounts payable and accrued liabilities as of June 30, 2023 and December 31, 2022, respectively. Moreover, there is a second vendor that accounted for approximately 41.1% and 33.6% of the total accounts payable and accrued liabilities as of June 30, 2023 and December 31, 2022, respectively, but we did not incur any expenses with this vendor during the three and six months ended June 30, 2023 and 2022.



We had a third vendor that accounted for approximately 26.7% and 19.7% of the general and administrative expenses for the three and six months ended June 30, 2023, respectively. This same vendor accounted for approximately 15.4% of the total accounts payable and accrued liabilities as of June 30, 2023.

#### 3. Brookline Merger

Under the Brookline Business Combination Agreement with BCAC, Legacy Apexigen was valued at \$205.0 million on a fully diluted basis, net of exercise proceeds for Legacy Apexigen's pre-closing stock options. On July 29, 2022, Legacy Apexigen and BCAC consummated the Brookline Merger with Legacy Apexigen surviving such merger as a wholly-owned subsidiary of BCAC. Also at closing of the Brookline Merger, BCAC changed its name to Apexigen, Inc. and Legacy Apexigen changed its name to Apexigen America, Inc.

Upon the closing of the Brookline Merger, we amended and restated our certificate of incorporation to, among other things, increase the total number of authorized shares of capital stock to 1,020,000,000 shares, of which 1,000,000,000 shares were designated common stock, \$0.0001 par value per share, and of which 20,000,000 shares were designated preferred stock, \$0.0001 par value per share.

Immediately prior to the closing of the Brookline Merger, each issued and outstanding share of Legacy Apexigen's convertible preferred stock, was converted into shares of common stock based on a one-to-one ratio (see Note 7). The Brookline Merger is accounted for with a retrospective application that results in 145,130,628 shares of convertible preferred stock converting into the same number of shares of Legacy Apexigen's common stock.

Upon the consummation of the Brookline Merger, each share of Legacy Apexigen common stock issued and outstanding was canceled and converted into the right to receive 0.102448 shares (the "Brookline Exchange Ratio") of BCAC's common stock (the "Per Share Merger Consideration").

Outstanding stock options, whether vested or unvested, to purchase shares of Legacy Apexigen's common stock granted under the 2010 Equity Incentive Plan and the 2020 Equity Incentive Plan ("Legacy Options") (see Note 8) converted into stock options for shares of our common stock upon the same terms and conditions that were in effect with respect to such stock options immediately prior to the Brookline Merger, after giving effect to the Brookline Exchange Ratio.

Outstanding warrants to purchase shares of common stock remained outstanding after the closing of the Brookline Merger. The warrants became exercisable 30 days after the completion of the Brookline Merger, subject to other conditions, including with respect to the effectiveness of a registration statement covering the shares of common stock underlying such warrants, and will expire five years after the completion of the Brookline Merger or earlier upon redemption or liquidation (see Note 2 and Note 7).

In connection with the Brookline Merger, certain stockholders exercised their right to redeem certain of their outstanding shares for cash, resulting in the redemption of 4,618,607 shares of common stock for gross redemption payments of \$47.2 million. In addition, a number of investors purchased an aggregate of 1,452,000 shares of common stock (the "PIPE Shares"), for a purchase price of \$10.00 per share, as applicable, for an aggregate purchase price of \$14.5 million pursuant to separate subscription agreements. The PIPE transaction closed simultaneously with the consummation of the Brookline Merger. In connection with the Brookline Merger and private offering in July 2022 (see Note 6), we incurred direct and incremental costs of approximately \$9.2 million related to the equity issuance, consisting primarily of investment banking, legal, accounting, and other professional fees, which we recorded to additional paid-in capital as a reduction of proceeds.

The Brookline Merger is accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, BCAC was treated as the "acquired" company for financial reporting purposes. Accordingly, for accounting purposes, the Brookline Merger was treated as the equivalent of Legacy Apexigen issuing stock for the net assets of BCAC, accompanied by a recapitalization. The net assets of BCAC are stated at historical cost, with no goodwill or intangible assets recorded.

Prior to the Brookline Merger, Legacy Apexigen and BCAC filed separate standalone federal, state, and local income tax returns. As a result of the Brookline Merger, we will file a consolidated income tax return. Although, for legal purposes, BCAC acquired Legacy Apexigen, and the Brookline Merger represents a reverse acquisition for federal income tax purposes. BCAC will be the parent of the consolidated group with Legacy Apexigen as a subsidiary, but in the year of the closing of the Brookline Merger, Legacy Apexigen will file a full-year tax return with BCAC joining in the return the day after the closing date of the Brookline Merger.

Upon closing of the Brookline Merger, we received gross proceeds of \$19.0 million from the Brookline Merger and PIPE financing, offset by transaction costs of \$9.2 million recorded in 2022 and BCAC's Extension and Working Capital Notes repayment



of \$0.9 million. The following table reconciles the elements of the Brookline Merger to the consolidated statements of cash flows and the consolidated statement of changes in stockholders' equity (in thousands):

| Cash - BCAC's trust (net of redemption)  | \$<br>4,435 |
|--|-------------|
| Cash - Private offering  | 14,520      |
| Less: BCAC's Extension and Working Capital Notes repayment in 2022                           | (861)       |
| Proceeds from Brookline Merger and private offering for the year ended December 31, 2022     | <br>18,094  |
| Less: transaction costs paid in 2022   | (9,221)     |
| Net proceeds from Brookline Merger and private offering for the year ended December 31, 2022 | 8,873       |
| Less: transaction costs paid in 2021   | (11)        |
| Plus: net assets of BCAC   | (394)       |
| Brookline Merger and private offering for the year ended December 31, 2022                   | \$<br>8,468 |

The number of shares of common stock issued immediately following the consummation of the Brookline Merger was:

| Common stock, outstanding prior to Brookline Merger             | 5,061,592   |
|---|-------------|
| Less: redemption of BCAC shares                                 | (4,618,607) |
| Common stock of BCAC  | 442,985     |
| BCAC Sponsor shares   | 1,190,979   |
| BCAC Representative shares                                      | 57,500      |
| Shares issued in private offering                               | 1,452,000   |
| Brookline Merger and July 2022 private offering shares          | 3,143,464   |
| Legacy Apexigen shares  | 18,147,032  |
| Total shares of common stock immediately after Brookline Merger | 21,290,496  |
| Exercise of Legacy Apexigen common stock warrant                | 4,539       |
| Shares issued to Lincoln Park (Note 6)                          | 150,000     |
| Total shares of common stock on July 29, 2022                   | 21,445,035  |

The number of Legacy Apexigen's shares was determined as follows:

|  | Legacy Apexigen<br>Shares | Legacy Apexigen<br>Shares, effected for<br>Brookline Exchange<br>Ratio |
|--|---------------------------|--|
| Balance as of December 31, 2020  | 30,521,693                | 3,126,980  |
| Recapitalization applied to Convertible Preferred Stock outstanding at December 31, 2020 | 145,130,628               | 14,868,374   |
| Exercise of common stock options - 2021  | 548,972                   | 56,238   |
| Exercise of common stock options - 2022 (pre-Closing)                                    | 702,074                   | 71,922   |
| Exercise of common stock restricted awards - 2022 (pre-Closing)                          | 229,556                   | 23,518   |
| Total Legacy Apexigen shares as of July 29, 2022   | 177,132,923               | 18,147,032   |

## 4. Fair Value Measurement

We record financial assets and liabilities at fair value. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value and expands disclosures about fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. We categorize assets and liabilities recorded at fair value in the consolidated financial statements based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

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

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of June 30, 2023, our cash equivalents consisted of money market funds with less than a three-month maturity. Our short-term investments was zero as of June 30, 2023. Money market funds are classified as Level 1 because they are valued using quoted market prices. As of December 31, 2022, we had short-term investments consisted of U.S. treasury securities and they are classified as Level 1 because they are valued using quoted market prices.

In certain cases where there is limited activity or less transparency around the inputs to valuation, we classify securities as Level 3. Level 3 liabilities consist of derivative warrant liabilities.

The following tables set forth the financial instruments that we measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

|   | June 30, 2023                   |    |                    |          |                  |          |                           |
|---|---------------------------------|----|--------------------|----------|------------------|----------|---------------------------|
|   | <br>Level 1                     | Le | evel 2             | Le       | vel 3            |          | Total                     |
| Financial assets:   |                                 |    |                    |          |                  |          |                           |
| Money market funds  | \$<br>8,039                     | \$ | -                  | \$       | -                | \$       | 8,039                     |
| Total   | \$<br>8,039                     | \$ | -                  | \$       | -                | \$       | 8,039                     |
| Financial liability:  |                                 |    |                    |          |                  |          |                           |
| Derivative warrant liabilities  | \$<br>-                         | \$ | -                  | \$       | -                | \$       | -                         |
| Total   | \$<br>-                         | \$ | -                  | \$       | -                | \$       | -                         |
|   |                                 |    |                    |          |                  |          |                           |
|   |                                 |    | <b>D</b> 1         | D4 0000  |                  |          |                           |
|   |                                 |    | December           | 31, 2022 |                  |          |                           |
|   | <br>Level 1                     | Le | December<br>evel 2 | -        | evel 3           |          | Total                     |
| Financial assets:   | <br>Level 1                     | Le |                    | -        |                  |          | Total                     |
| Financial assets:<br>Money market funds   | \$<br>Level 1<br>14,671         | £  |                    | -        |                  | \$       | <b>Total</b><br>14,671    |
|   |                                 |    | evel 2             | Le       | evel 3           | \$       |                           |
| Money market funds  | 14,671                          |    | evel 2             | Le       | evel 3           | \$<br>\$ | 14,671                    |
| Money market funds<br>U.S. treasury securities                                  | \$<br>14,671<br>1,997           | \$ | evel 2             | Le<br>\$ | evel 3           |          | 14,671<br>1,997           |
| Money market funds<br>U.S. treasury securities<br>Total                         | \$<br>14,671<br>1,997           | \$ | evel 2             | Le<br>\$ | evel 3           |          | 14,671<br>1,997           |
| Money market funds<br>U.S. treasury securities<br>Total<br>Financial liability: | \$<br>14,671<br>1,997<br>16,668 | \$ |                    | Le       | -<br>-<br>-<br>- | \$       | 14,671<br>1,997<br>16,668 |

The derivative warrant liabilities had a fair value of zero and \$11,000 as of June 30, 2023 and December 31, 2022, respectively. We estimate the fair value of the derivative warrant liabilities using a Black-Scholes option-pricing model, which assumptions are related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock warrants based on historical volatility of select peer company's common stock that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which we anticipate remaining at zero.

The following tables summarize the estimated fair value of our marketable securities and the gross unrealized holding gains and losses (in thousands):

|                                 | June 30, 2023 |                  |    |       |        |      |    |                     |
|---------------------------------|---------------|------------------|----|-------|--------|------|----|---------------------|
|                                 |               |                  |    | Unrea | alized |      |    |                     |
|                                 |               | nortized<br>Cost | G  | ains  | Lo     | sses |    | timated<br>ir Value |
| Cash and cash equivalents:      |               |                  |    |       |        |      |    |                     |
| Cash                            | \$            | 1,330            | \$ | -     | \$     | -    | \$ | 1,330               |
| Money market funds              |               | 8,039            |    | -     |        | -    |    | 8,039               |
| Total cash and cash equivalents | \$            | 9,369            | \$ | -     | \$     | -    | \$ | 9,369               |

|                                 | December 31, 2022 |                  |    |       |        |        |    |                       |
|---------------------------------|-------------------|------------------|----|-------|--------|--------|----|-----------------------|
|                                 |                   |                  |    | Unrea | alized |        |    |                       |
|                                 | Aı                | nortized<br>Cost |    | Gains |        | Losses |    | stimated<br>air Value |
| Cash and cash equivalents:      |                   |                  |    |       |        |        |    |                       |
| Cash                            | \$                | 131              | \$ | -     | \$     | -      | \$ | 131                   |
| Money market funds              |                   | 14,671           |    | -     |        | -      |    | 14,671                |
| Total cash and cash equivalents | \$                | 14,802           | \$ | -     | \$     | -      | \$ | 14,802                |
| Marketable securities:          |                   |                  | _  |       |        |        |    |                       |
| U.S. treasury securities        | \$                | 1,997            | \$ | -     | \$     | -      | \$ | 1,997                 |
| Total marketable securities     | \$                | 1,997            | \$ | _     | \$     | -      | \$ | 1,997                 |

## 5. Balance Sheet Components

## Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

|   | une 30,<br>2023 | Dec | ember 31,<br>2022 |
|---|-----------------|-----|-------------------|
| Prepaid clinical development expenses           | \$<br>959       | \$  | 1,128             |
| Prepaid insurance expenses                      | 210             |     | 970               |
| Other prepaid expenses and current assets       | 286             |     | 520               |
| Total prepaid expenses and other current assets | \$<br>1,455     | \$  | 2,618             |

## Property and Equipment, Net

We moved to a new office in March 2023 and do not use any significant property and equipment as of June 30, 2023. During the three months ended March 31, 2023, we sold our laboratory equipment for \$150,000 and disposed of our remaining property and equipment as we prepared to vacate our prior office and laboratory space. We recognized a gain on disposals of approximately \$16,000 from the sale of our laboratory equipment for the three months ended March 31, 2023. Property and equipment, net, consists of the following (in thousands):

|                                   | June<br>202 |   | December 31,<br>2022 |       |  |
|-----------------------------------|-------------|---|----------------------|-------|--|
| Laboratory equipment              | \$          | - | \$                   | 909   |  |
| Furniture and fixtures            |             | - |                      | 28    |  |
| Office equipment                  |             | - |                      | 25    |  |
| Software                          |             | - |                      | 12    |  |
| Total property and equipment      |             | - |                      | 974   |  |
| Less: accumulated depreciation    |             | - |                      | (824) |  |
| Total property and equipment, net | \$          | - | \$                   | 150   |  |

Depreciation expense for property and equipment was zero and \$28,000 for the three months ended June 30, 2023 and 2022, respectively, and \$17,000 and \$55,000 for the six months ended June 30, 2023 and 2022, respectively.

## Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

|  | J  | une 30,<br>2023 | Dec | ember 31,<br>2022 |
|--|----|-----------------|-----|-------------------|
| Accrued clinical trial and manufacturing costs | \$ | 3,850           | \$  | 4,340             |
| Accrued personnel costs                        |    | 601             |     | 497               |
| Accrued legal expenses                         |    | 335             |     | 84                |
| Other accrued liabilities                      |    | 576             |     | 438               |
| Total accrued liabilities                      | \$ | 5,362           | \$  | 5,359             |

## 6. Stockholder's Equity

#### **Preferred Stock**

As discussed in Note 3, *Brookline Merger*, we retroactively adjusted the shares issued and outstanding prior to July 29, 2022 to give effect to the Brookline Exchange Ratio established in the Brookline Business Combination Agreement to determine the number of shares of common stock into which they were converted.

Prior to the Brookline Merger, Legacy Apexigen had shares of \$0.001 par value Series A-1, Series A-2, Series B, and Series C preferred stock outstanding, all of which were convertible into shares of common stock of Legacy Apexigen on a 1:1 basis, subject to certain anti-dilution protections. Upon the closing of the Brookline Merger, the outstanding shares of preferred stock were converted into common stock of Legacy Apexigen, and then into common stock of Apexigen at a ratio of 1:0.102448, the exchange rate established in the Brookline Business Combination Agreement.

|                              | Jul                       | July 29, 2022 (Closing Date) |                        |  |  |  |  |  |
|------------------------------|---------------------------|------------------------------|------------------------|--|--|--|--|--|
| Convertible Preferred Stock  | Preferred Stock<br>Shares | Brookline<br>Exchange Ratio  | Common Stock<br>Shares |  |  |  |  |  |
| Series A-1 (pre-combination) | 39,196,116                | 0.102448                     | 4,015,564              |  |  |  |  |  |
| Series A-2 (pre-combination) | 12,625,343                | 0.102448                     | 1,293,442              |  |  |  |  |  |
| Series B (pre-combination)   | 14,218,546                | 0.102448                     | 1,456,662              |  |  |  |  |  |
| Series C (pre-combination)   | 79,090,623                | 0.102448                     | 8,102,706              |  |  |  |  |  |
| Total                        | 145,130,628               |                              | 14,868,374             |  |  |  |  |  |

As of June 30, 2023, we are authorized to issue 20,000,000 shares of preferred stock with a par value of \$0.0001 per share. The board of directors (the "Board") has the authority to issue preferred stock and to determine the rights, privileges, preferences, restrictions, and voting rights of those shares. As of June 30, 2023, we had no shares of preferred stock outstanding.

## **Common Stock**

The holders of common stock are entitled to one vote per share on all matters to be voted on by the stockholders of Apexigen. Subject to the preferences that may be applicable to any outstanding shares of the convertible preferred stock, the holders of the common stock are entitled to receive ratably such dividends, if any, as the Board may declare. The Board has declared no dividends to date.

At June 30, 2023, we had reserved the following shares of common stock for the following purposes:

| Equity awards issued and outstanding              | 5,173,387  |
|---|------------|
| Equity awards available for future grants         | 1,672,531  |
| Shares available for Employee Stock Purchase Plan | 466,801    |
| Common stock warrants                             | 5,819,934  |
| Total common stock reserved for issuance          | 13,132,653 |

## **Private Offerings**

In March 2022, we entered into subscription agreements with certain investors for a private investment in public equity transaction ("2022 PIPE") to close concurrently with the Brookline Merger (see Note 3). In July 2022, we received aggregate gross proceeds of \$19.0 million funded by \$4.5 million in cash held in BCAC's trust account net of redemption and \$14.5 million from the 2022 PIPE. The aggregate gross proceeds were offset by transaction costs of \$9.2 million and payments of previous BCAC's debts totaled \$0.9 million. The PIPE investors ("2022 PIPE Investors") received an aggregate of 1,452,000 unit (each a "2022 PIPE Unit") at a purchase price of \$10.00 per unit. Each 2023 PIPE Unit consists of one share of common stock and one-half of one warrant. Each whole warrant entitles the 2022 PIPE Investors to purchase one share of common stock at exercise price of \$11.50 per share during the period commencing six months after July 29, 2022 and terminating on five-year anniversary of July 29, 2022, or earlier upon redemption or liquidation.

In January 2023, we received aggregate gross proceeds of \$2.8 million from a private investment in public equity transaction ("2023 PIPE"). The aggregate gross proceeds were offset by transaction costs of \$0.7 million recorded in 2023, where \$0.6 million were paid during the six months ended June 30, 2023 and approximately \$43,000 were accrued as of June 30, 2023. The PIPE investors ("2023 PIPE Investors") received an aggregate of 1,995,708 unit (each a "2023 PIPE Unit") at a purchase price of \$1.40 per unit. Each 2023 PIPE Unit consists of one share of common stock and one warrant. Each warrant entitles the 2023 PIPE Investors to purchase one share of common stock at an exercise price of \$1.40 per share during the period commencing six months after January

30, 2023 and terminating on July 30, 2028, or earlier upon redemption or liquidation. We also entered into a letter agreement with the placement agent, pursuant to which it served as the exclusive placement agent for us in connection with the 2023 PIPE. We paid the placement agent a cash fee equal to 7% of the aggregate gross proceeds from the 2023 PIPE. The placement agent received warrants to purchase up to 99,785 shares of common stock on substantially the same terms as the 2023 PIPE warrants, except that the placement agent's warrants have an exercise price equal to 125% of the price paid by investors in the 2023 PIPE, or \$1.75 per share of common stock.

#### Lincoln Park

In conjunction with the Brookline Merger, we entered into an equity line agreement and a registration rights agreement ("RRA") with Lincoln Park in March 2022, which provides that we may sell to Lincoln Park up to \$50.0 million of shares (the "Purchase Shares") of our common stock. The aggregate number of shares that we can sell to Lincoln Park under the equity line agreement may not exceed 4.99% of the outstanding common stock, subject to certain exceptions set forth in the equity line agreement.

At the closing of the Brookline Merger, we issued 150,000 shares of common stock to Lincoln Park as an initial fee for its commitment to purchase shares of our common stock under the equity line agreement. On the date that is 90 calendar days after the Brookline Merger, we were obligated to issue additional commitment shares to Lincoln Park, calculated as the lesser of (i) \$1.5 million of shares of common stock at a price per share equal to the arithmetic average of the closing sale price for our common stock during the ten consecutive business days immediately preceding the share delivery date and (ii) 500,000 shares of common stock. We issued 500,000 additional commitment shares to Lincoln Park in October 2022 and the liability was remeasured. Change in fair value of liability for common stock to be issued was approximately \$205,000 for the year ended December 31, 2022.

Subject to the terms of the equity line agreement, we have the right, in our sole discretion, to present Lincoln Park with a purchase notice (a "Regular Purchase Notice"), provided that the closing stock price of the common stock on the Nasdaq is not below \$3.00 per share. Each Regular Purchase Notice would direct Lincoln Park to purchase up to \$500,000 of Purchase Shares (a "Regular Purchase"), which amounts may be increased under certain circumstances. Lincoln Park's obligation under any single Regular Purchase generally will not exceed \$1.0 million. The equity line agreement provides for a purchase price per Purchase Shares for each Regular Purchase (the "Purchase Price") equal to the lesser of (i) the lowest sale price of the common stock on the Nasdaq on the purchase date of such shares; and (ii) the average of the three lowest closing sale prices for the common stock traded on the Nasdaq during the ten consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition, on any date on which we submit a Regular Purchase Notice for the maximum amount allowed for such a Regular Purchase to Lincoln Park, we also have the right, in our sole discretion, to present Lincoln Park with an accelerated purchase notice (an "Accelerated Purchase Notice"), directing Lincoln Park to purchase an amount of Purchase Shares (an "Accelerated Purchase"), which number of Purchase Shares will not exceed the lesser of (i) 300% of the number of shares purchased pursuant to such Regular Purchase Notice and (ii) 30% of the total volume of shares of the common stock traded on the Nasdaq during the Accelerated Purchase period. The purchase price per Purchase Share for each such Accelerated Purchase will be equal to the lesser of 95% of (i) the volume-weighted average price of the common stock on the Nasdaq during the applicable Accelerated Purchase period on the applicable Accelerated Purchase date; and (ii) the closing sale price of the common stock on the Nasdaq on the applicable Accelerated Purchase date. Lincoln Park has no obligation to purchase shares under the equity line agreement unless we comply with the terms of the RRA.

In September 2022, we received aggregate proceeds of \$2.5 million from Regular Purchases of 616,684 shares of common stock under the equity line agreement. For the six months ended June 30, 2023, we did not meet the aforementioned requirements for Lincoln Park to purchase common stock under the equity line agreement.

#### 7. Public and Private Warrants

Prior to the Brookline Merger, BCAC issued 2,875,000 shares of public warrants and 123,500 shares of private warrants in connection with BCAC's initial public offering. In connection with the closing of the 2022 and 2023 PIPE transactions on July 29, 2022 and January 30, 2023, respectively (see Note 6), we issued 726,000 and 2,095,493 public warrants, respectively. As of June 30, 2023, we had 1,995,708 public warrants outstanding with an exercise price of \$1.40, 99,785 public warrants outstanding with an exercise price of \$1.75 per share, 3,601,000 public warrants outstanding with an exercise price of \$11.50 per share, and 123,500 private placement warrants outstanding with an exercise price of \$11.50 per share. Each of these warrants with an exercise price of \$11.50 became exercisable on August 28, 2022, which was 30 days after July 29, 2022, and will expire on the fifth anniversary of July 29, 2022, or earlier upon redemption or liquidation. Each of these warrants with an exercise price of \$1.40 or \$1.75 become

exercisable commencing six months after January 30, 2023, and will expire on July 30, 2028, or earlier upon redemption or liquidation.

We may call the public warrants for redemption:

- in whole or in part;
- at a price of \$0.01 per warrant;
- upon a minimum of 30 days' prior written notice of redemption; and
- if, and only if, the last reported closing price of the ordinary shares equals or exceeds \$18.00 per share for any 20 trading days within a 30-trading day period on the third trading day prior to the date on which we send the notice of redemption to the warrant holders.

If we call the public warrants for redemption, management will have the option to require all holders that wish to exercise the public warrants to do so on a "cashless basis," as described in the warrant agreement.

The private placement warrants are identical to the public warrants, except that none of the private placement warrants will be redeemable so long as they are held by the initial purchasers or any of their permitted transferees. As of June 30, 2023, the private placement warrants had been transferred from the initial purchaser to other individuals, at which time the terms of the private placement warrants became identical to the public warrants. As a result, the derivative warrant liabilities were revalued on the transfer date and reclassified to additional paid-in capital. The change in fair value of derivative warrant liability on the transfer date was not significant.

The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a share dividend, recapitalization, reorganization, merger, or consolidation. However, the warrants will not be adjusted for issuance of common stock at a price below its exercise price.

In connection with the 2022 PIPE and 2023 PIPE (see Note 6), we issued public warrants to purchase 726,000 and 2,095,493 shares of the Company's common stock, on July 29, 2022 and January 30, 2023, respectively. We measured the public warrants based on the estimated grant date fair value. We included the fair value of the 2022 and 2023 public warrants, totaling \$3.5 million and \$1.1 million, respectively, as a component of the private offering within the additional paid-in capital in the consolidated statements of stockholders' equity for the year ended December 31, 2022 and for the three months ended March 31, 2023. The fair values of the 2022 and 2023 public warrants totaling \$3.5 million and \$1.1 million, respectively, were also a non-cash financing activity for the year ended December 31, 2022 and for three months ended March 31, 2023. In determining the fair value of the public warrants, we used the Black-Scholes option-pricing model and the following assumptions:

|                         | July 29, 2022 | January 30, 2023 |
|-------------------------|---------------|------------------|
| Expected term (years)   | 5.00          | 5.00             |
| Expected volatility     | 87.90%        | 82.40 %          |
| Risk-free interest rate | 2.70 %        | 3.60 %           |
| Expected dividend       | 0.00%         | 0.00%            |

The assumptions used to determine the fair value of the public warrants are as follows:

- Expected volatility: Because our stock is recently traded in an active market, we calculate volatility by using the historical volatilities of the common stock of comparable publicly traded companies. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the public warrants.
- Risk-free interest rate: we base the risk-free interest rate from the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected term.
- Expected term: we determine the expected life of public warrants over the period when the share public warrants are vested and ending on the date when the share public warrants would expire.
- Expected dividend yield: we have never paid cash dividends on our common stock and do not have plans to pay cash dividends in the future. Therefore, we use an expected dividend yield of zero.



### 8. Equity Plans and Related Equity Activities

#### **Equity Incentive Plans**

In December 2010, we adopted the 2010 Stock Incentive Plan and 2010 Equity Incentive Plan, both of which expired in 2020. In August 2020, we adopted the 2020 Equity Incentive Plan. Upon the close of the Brookline Merger, we adopted the 2022 Equity Incentive Plan (the "2022 Plan", and together with, the 2020 Equity Incentive Plan, the 2010 Stock Incentive Plan and the 2010 Equity Incentive Plan, collectively, the "Plans"). No further grants will be made under the 2020 Equity Incentive Plan. The 2022 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit, performance stock awards, and other forms of equity awards as described in the 2022 Plan.

Initially, the maximum number of shares of common stock reserved for issuance under the 2022 Plan was 2,573,405 shares, plus any shares that may be added to the 2022 Plan's reserve if awards from the 2010 Equity Incentive Plan or 2020 Equity Incentive Plan expire, are canceled or otherwise terminate, up to a maximum of 3,461,319 shares added from such expirations, cancellations, and terminations. As of June 30, 2023, Apexigen had reserved 6,845,918 shares of common stock for the issuance of incentive and non-statutory stock options to purchase common stock, stock awards, and restricted stock awards to employees, directors, and consultants under the Plans. The number of shares of common stock reserved for issuance under the 2022 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2023 through January 1, 2032, in an amount equal to the lesser of (1) 5.0% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (2) 3,216,756 shares, or (3) such number of shares determined by the administrator of the 2022 Plan. On January 1, 2023, the number of shares of common stock reserved for issuance under the 2022 Plan automatically increased by 1,132,300 shares.

The Board determines the period over which options become exercisable and options generally vest over a four-year period. No option will become exercisable after the expiration of ten years from the date of grant. The term of an incentive stock option ("ISO") granted to a 10% stockholder will not exceed five years from the date of the grant. The exercise price of an ISO and non-statutory stock option ("NSO") will not be less than 100% of the estimated fair value of the shares on the date of grant, and the exercise price of an ISO and NSO granted to a 10% stockholder will not be less than 110% of the estimated fair value of the shares on the date of grant.

#### **Equity Plan Activities - Board Members**

In February 2021, we entered into a consulting agreement with a Board member and granted an option (the "Stock Option") to acquire 20,489 shares of common stock. The Stock Option vests upon the achievement of certain performance milestones and has a ten-year term. Based on the guidance in ASC Topic 718, *Stock Compensation*, we concluded that the Stock Option is a performance-based stock option. As determined by the Board, we achieved one of the performance milestones under the Stock Option during 2021. As a result, 5,122 options vested in 2021, and we recognized \$20,000 of stock-based compensation expense in 2021. No other performance milestone had been achieved as of June 30, 2023. The unrecognized stock-based compensation expense for this option as of June 30, 2023 was approximately \$60,000.

In September 2022, we granted options to purchase 700,000 shares of common stock to our non-executive Board members at an exercise price of \$2.65 per share pursuant to our Outside Director Compensation Policy. These options vest over 3 years in equal annual installments. The weighted average grant date fair value per option was \$1.96 and the fair value of these options is approximately \$1.3 million. We recorded \$0.1 million as stock-based compensation expense during the three months ended June 30, 2023. The unrecognized stock-based compensation expense for these options as of June 30, 2023 is approximately \$1.1 million.

#### **Equity Plan Activities - Restricted Stock Units**

In October 2022, we granted restricted stock units ("RSUs") for 243,618 shares of common stock to various employees, all of which were fully vested as of June 30, 2023. The weighted average grant date fair value per RSU was \$2.46 and the fair value of these RSUs is approximately \$0.6 million. We amortize the fair value of the RSUs on a straight-line basis over the applicable vesting periods. 50% of these RSUs vested in December 2022 and the remaining 50% vested in June 2023. On December 15, 2022, 80,668 shares were vested and issued for common stock, and 41,136 shares were forfeited to cover tax related withholdings. On December 16, 2022, 1,279 shares were cancelled. 12,942 shares were vested and issued for common stock during the six months ended June 30, 2023 upon satisfaction of severance conditions and 8,454 shares were forfeited to cover tax related withholdings. On June 15, 2023, 64,448 shares were vested and issued for common stock and 34,691 shares were forfeited to cover tax related withholdings. We recorded \$0.1 million and \$0.3 million as operating expense related to these RSUs during the three and six months ended June 30, 2023, respectively.

In March 2023, we granted RSUs for 482,500 shares of common stock to certain of our employees. The weighted average grant date fair value per RSU was \$0.52 and the fair value of these RSUs is approximately \$0.2 million. We amortize the fair value of the RSUs on a straight-line basis over its vesting periods. The RSUs vest based on different milestones or periods. Additionally, any unvested RSUs shall be fully vested upon satisfaction of severance conditions. 5,922 shares were vested and issued for common stock



during the six months ended June 30, 2023 upon satisfaction of severance conditions and 4,078 shares were forfeited to cover tax related withholdings. On May 23, 2023, 108,047 shares were vested and issued for common stock and 55,953 shares were forfeited to cover tax related withholdings. We recorded \$0.1 million as operating expense related to these RSUs during the three and six months ended June 30, 2023. The unrecognized stock-based compensation expense for these RSUs as of June 30, 2023 was approximately \$0.1 million.

In May 2023, we granted RSUs for 400,000 shares of common stock to an executive. The weighted average grant date fair value per RSU was \$0.42 and the fair value of these RSUs is approximately \$0.2 million. The RSUs vest upon the achievement of certain performance milestones. No milestone was achieved as of June 30, 2023. The unrecognized stock-based compensation expense for these RSUs as of June 30, 2023 was approximately \$0.2 million.

#### **Equity Plan Activities - Stock Options**

There were no options granted during the six months ended June 30, 2023. During the six months ended June 30, 2022, we granted options to purchase 552,937 shares of common stock with a weighted-average exercise price of \$4.94 per share. For the options granted during the six months ended June 30, 2022, we expect to recognize \$1.8 million of stock-based compensation over the related vesting period. The weighted-average grant date fair value of options granted during the six months ended June 30, 2022 was \$3.28 per share. During the six months ended June 30, 2023 and 2022, options to purchase 254,132 shares and 591,498 shares, respectively, were canceled, with a weighted-average exercise price of \$3.59 and \$2.34 per share, respectively. There were no options exercised during the six months ended June 30, 2023. For the six months ended June 30, 2022, the aggregate intrinsic value of the options exercised was \$0.1 million.

#### **Equity Stock Purchase Plan**

In August 2022, we adopted the Apexigen, Inc. 2022 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides eligible employees with a means of acquiring shares of our common stock at a discounted purchase price using their own accumulated payroll deductions. Under the terms of the ESPP, eligible employees can elect to have up to 15% of their eligible compensation, up to a maximum of \$25,000 per year, withheld to purchase shares of common stock for a purchase price equal to 85% of the lower of the fair market value per share of common stock on (i) the commencement date of the 24-month offering period or (ii) the respective purchase date.

As of June 30, 2023, Apexigen had reserved 466,801 shares of common stock under purchase rights granted to our eligible employees or to eligible employees of any of our designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2023 through January 1, 2032, by the lesser of (1) 1.0% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (2) 536,126 shares; provided that before the date of any such increase, our Board may determine that such increase will be less than the amount set forth in clauses (1) and (2). On January 1, 2023, the number of shares of common stock reserved for issuance under the ESPP automatically increased by 226,460 shares.

The initial offering period commenced in November 2022. As of June 30, 2023, 17,000 shares of common stock were purchased under the ESPP. There was approximately \$36,000 of stock-based compensation expense related to the ESPP reversed during the six months ended June 30, 2023 due to withdrawals. As of June 30, 2023, there was no unrecognized stock-based compensation cost related to ESPP. As of June 30, 2023, 466,801 shares were available under the ESPP for future issuance.

#### Stock-Based Compensation

Stock-based compensation is included in the consolidated statements of operations and comprehensive loss in research and development and general and administrative expense depending on the nature of the services provided. The following table illustrates stock-based compensation expense related to stock options granted under the Plans recognized for the three and six months ended June 30, 2023 and 2022 (in thousands):

|                                | Three Months Ended<br>June 30, |      |    | Six Months Ended<br>June 30, |    |      |    |      |
|--------------------------------|--------------------------------|------|----|------------------------------|----|------|----|------|
|                                |                                | 2023 |    | 2022                         |    | 2023 |    | 2022 |
| Research and development       | \$                             | 46   | \$ | 139                          | \$ | 144  | \$ | 258  |
| General and administrative     |                                | 307  |    | 229                          |    | 696  |    | 531  |
| Total stock-based compensation | \$                             | 353  | \$ | 368                          | \$ | 840  | \$ | 789  |

As of June 30, 2023, there was \$3.1 million of unrecognized stock-based compensation cost related to stock options granted to employees and others under the Plans, which we expect to recognize over a weighted average period of 2.2 years.

#### 9. Commitments and Contingencies

## Indemnification

As permitted under Delaware law and in accordance with our bylaws, we have agreed to indemnify our officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity. The term of the indemnification period is equal to the officer's or director's lifetime.

The maximum amount of potential future indemnification is unlimited. However, we currently hold director and officer liability insurance, which limits our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations for any period presented.

We have certain agreements with service providers and other parties with which we do business that contain indemnification provisions pursuant to which we have agreed to indemnify the party against certain types of third-party claims. It is not possible to determine the maximum potential amount under these indemnification agreements due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement. Since these agreements were effective after June 30, 2023, there were no payments made by us under these agreements as of June 30, 2023. As of June 30, 2023, there was not a reasonable possibility that we had incurred a material loss with respect to indemnification of such parties. We had not recorded any liability for costs related to indemnification through June 30, 2023.

#### **Clinical Collaborations**

We have entered into a number of collaboration arrangements for the clinical development of sotigalimab with companies and academic and nonprofit institutions. These arrangements specify whether we or the collaborator bears the cost of the clinical trials, and in the case of combination therapies, typically the collaborators provide the supply of such drug products while we supply sotigalimab. Our applicable share of the costs of these clinical collaborations are reflected as research and development expenses.

Upon achievement of certain regulatory and clinical milestones related to the development of sotigalimab in pancreatic cancer, we will be obligated to pay an aggregate of up to \$9.5 million in cash and shares of common stock. Because we are not currently advancing the development of sotiga in pancreatic cancer, none of these milestones were probable as of June 30, 2023, and no amounts have been recognized.

#### Severance

The Board approved severance plans for certain executive officers and employees in 2022 and May 2023. The severance liability is contingent upon multiple triggers, including a change-in-control event and involuntary termination within 12 months of a change-in-control event. When these severance conditions become probable, we may be obligated to pay up to \$5.3 million in cash to such eligible executive officers and employees under the severance plans. Because the Pyxis Merger (see Note 1) is not yet completed and terminations are not yet determined, the severance liability was not probable as of June 30, 2023, and no amounts have been recorded.

## Other

No liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded as it is not probable that a liability has been incurred and the amount cannot be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred. We enter into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and contract manufacturing organizations for the manufacture of clinical trial materials.

## 10. Income Taxes

The effective tax rate for the three and six months ended June 30, 2023 and 2022 was zero. The difference between the effective income tax rate and the U.S. federal statutory rate of 21% is primarily attributable to recording valuation allowances to offset deferred tax assets arising from federal and state net operating losses.



## 11. Net Loss Per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

|  | As of Ju   | As of June 30, |  |  |  |
|--|------------|----------------|--|--|--|
|  | 2023       | 2022           |  |  |  |
| Equity awards                            | 5,173,387  | 3,447,426      |  |  |  |
| Common stock warrants                    | 5,819,934  | 13,361         |  |  |  |
| Total common stock reserved for issuance | 10,993,321 | 3,460,787      |  |  |  |

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

The following discussion and analysis provide information which Apexigen's management believes is relevant to an assessment and understanding of Apexigen's results of operations and financial condition. You should read the following discussion and analysis of Apexigen's results of operations and financial condition together with Apexigen's consolidated financial statements and related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q as well as our Annual Report on Form 10-K for the year ended December 31, 2022. In addition to historical financial information, this discussion contains forward-looking statements based upon Apexigen's current expectations that involve risks and uncertainties, including those described in the section titled, "Special Note Regarding Forward-Looking Statements." Apexigen's actual results could differ materially from such forward-looking statements as a result of various factors, including those set forth under "Risk Factors" in this Quarterly Report on Form 10-Q. Unless otherwise indicated or the context otherwise requires, references included in this section to "Apexigen," "Apexigen's, "the Company," "the Company's," "we," "our," "us," and "its" refer to Apexigen.

## **Business Overview**

We are a clinical-stage biopharmaceutical company focused on discovering and developing a new generation of antibody therapeutics for oncology, with an emphasis on new immuno-oncology agents designed to harness the patient's immune system to combat and eradicate cancer. We and our licensees are researching and developing several protein therapeutics that were discovered using our APXiMAB antibody platform. We have one clinical-stage candidate, sotigalimab ("sotiga" or "APX005M") that we are developing. We also have several preclinical and research stage antibodies we discovered using our APXiMAB platform that we are not currently advancing as we focus our resources on completing ongoing clinical development and conducting manufacturing activities to support our sotiga program. Our licensees are advancing five product candidates in clinical development that were enabled by discoveries from our APXiMAB platform.

Our clinical-stage candidate, sotiga, is a humanized agonist antibody that targets and activates CD40, a co-stimulatory receptor that is essential for activating both the innate and adaptive arms of the immune system, to stimulate an anti-tumor immune response. Sotiga is currently in Phase 2 clinical development for the treatment of solid tumors such as soft tissue sarcomas, and melanoma in combination with chemotherapy, radiation therapy and immunotherapy.

Our APXiMAB platform was used to enable the discovery of multiple protein therapeutic product candidates against a variety of molecular targets, including targets that are difficult to drug with conventional antibody technologies. In addition to the product candidates that we wholly own, several product candidates discovered through the use of the APXiMAB platform are in clinical development by our licensees. The most advanced of these programs is Novartis' Beovu® (brolucizumab-dbll) product, which received FDA approval in 2019 and is marketed in over 70 countries. Two other programs being developed by our licensees are in later-stage development; Simcere's suvemcitug (BD0801) is in Phase 3 clinical development in ovarian cancer and Mabwell's 9MW0211 is in an adaptive, pivotal Phase 2/3 clinical trial in wet age-related macular degeneration ("AMD"). There is no guarantee that any of the product candidates discovered using our APXiMAB antibody platform, whether developed by us or our licensees, will receive regulatory approval.

In March 2022, Brookline Capital Acquisition Corp. ("BCAC") and Apexigen America, Inc., which was then known as Apexigen, Inc. ("Legacy Apexigen"), entered into a business combination agreement ("Brookline Business Combination Agreement") pursuant to which BCAC and Legacy Apexigen agreed to combine, with Legacy Apexigen's equityholders owning a majority of the equity in the combined public company. The transactions contemplated under the Brookline Business Combination Agreement (the "Brookline Merger") closed in July 2022. At that time, a subsidiary of BCAC merged with and into Legacy Apexigen with Legacy Apexigen surviving the Brookline Merger as a wholly owned subsidiary of BCAC. Additionally, BCAC changed its name to Apexigen, Inc. and Legacy Apexigen changed its name to Apexigen America, Inc.

We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the issuance of stock as well as through proceeds from license agreements. Our net losses were \$6.0 million and \$8.1 million for the three months ended June 30, 2023 and 2022, respectively, and \$12.1 million and \$17.1 million for the six months ended June 30, 2023 and 2022, . We expect to continue to incur significant losses for the foreseeable future. As of June 30, 2023, we had an accumulated deficit of \$188.9 million.

On February 27, 2023, we announced that we were implementing a corporate restructuring to extend our cash runway as we reviewed and explored strategic alternatives. As part of the restructuring, which was approved by our Board on February 23, 2023, we announced plans to eliminate up to 11 of our 20 employee positions. We eliminated nine employee positions as of June 30, 2023. As a result of the restructuring, we incurred severance costs of \$0.1 million and \$0.4 million during the three and six months ended June 30, 2023, respectively. We expect our operating expenses to decrease in the near term as we have paused enrollment in our clinical trials with the exception of the investigator-sponsored trial in patients with dedifferentiated liposarcoma and otherwise slowed or paused the



advancement of our programs in order to reduce our expenses as we pursue strategic alternatives. We expect our operating expenses would increase if we were to resume advancing the development of our programs and pursuing regulatory approvals for and preparing for the potential commercialization of our product candidates, in particular in the near term to advance sotiga into additional and potentially registration-enabling clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

If we do not consummate the Pyxis Merger (as defined below), we would need substantial additional funding to support our continuing operations and pursue our long-term development strategy. We would need to seek additional funding through the issuance of common stock, other equity or debt financings, or collaborations or partnerships with other companies if we were to independently continue our operations. The amount and timing of our future funding requirements would depend on many factors, including the pace and results of our clinical development efforts for our product candidates and other research, development, manufacturing, and commercial activities.

#### **Recent Developments**

On April 11, 2023, we received a written notice from the Listing Qualifications Staff of the Nasdaq Stock Market ("Nasdaq") notifying the Company that it has not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5450(a)(1) for a period of 30 consecutive business days (the "Notice"). This Notice has no immediate effect on the listing of our stock on the Nasdaq Capital Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a compliance period of 180 calendar days from the date of the Notice to regain compliance with the minimum closing bid price requirement. If we do not regain compliance during the compliance period, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we must meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market (with the exception of the minimum bid price requirement) and notify Nasdaq of our intent to cure the deficiency by effecting a reverse stock split if necessary. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, our stock will be subject to delisting.

We can achieve compliance with the minimum bid price requirement if, during either compliance period, the closing bid price per share of our stock is at least \$1.00 for a minimum of ten consecutive business days.

We intend to monitor the closing bid price of our stock and assess potential actions to regain compliance, but there can be no assurance that we will regain compliance with the minimum bid price requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

On May 23, 2023, we entered into an Agreement and Plan of Merger (the "Pyxis Merger Agreement") with Pyxis Oncology, Inc. ("Pyxis Oncology") and Ascent Merger Sub Corp., a wholly-owned subsidiary of Pyxis Oncology ("Merger Sub"), pursuant to which Merger Sub will merge with us (the "Pyxis Merger"), with Apexigen surviving such merger as a wholly-owned subsidiary of Pyxis Oncology. The Pyxis Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. On June 30, 2023, we filed a definitive merger proxy statement announcing a special meeting of Apexigen stockholders to be held virtually on August 22, 2023. Holders of our common stock as of the close of business on June 28, 2023 (the "Record Date") are entitled to vote at the special meeting. The completion of the Pyxis Merger is subject to the satisfaction or waiver of certain closing conditions, including the approval of the adoption of the Pyxis Merger Agreement by a majority of our outstanding shares of common stock as of the Record Date. At the closing, each share of Apexigen's common stock, equity awards, and warrants will automatically be converted into the right to receive 0.1725 (the "Exchange Ratio") shares of Pyxis Oncology's common stock, equity awards, and warrants, respectively.

### **Components of Results of Operations**

#### **Operating Expenses**

#### Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of sotiga, our lead product candidate, as well as APX601 and other preclinical product candidates. We expense research and development costs as incurred. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. We expense the prepaid amounts as the related goods are delivered or the services are performed.



Research and development expenses include:

- Expenses incurred under agreements with third-party contract research organizations for clinical development;
- Costs related to production of drug substance, drug product and clinical supply, including fees paid to third-party contract manufacturers;
- Laboratory and vendor expenses related to the execution of preclinical activities;
- Employee-related expenses, which include salaries, benefits and stock-based compensation; and
- Facilities, depreciation and amortization, insurance and other direct and allocated expenses incurred in our research and development activities

The following table summarizes our research and development expenses incurred for the periods presented (in thousands):

|   | Т  | Three Months Ended June 30, |         |       |    | Six Months Ended June 30, |    |        |  |  |  |
|---|----|-----------------------------|---------|-------|----|---------------------------|----|--------|--|--|--|
|   |    | 2023                        |         | 2022  |    | 2023                      |    | 2022   |  |  |  |
|   |    | (Unau                       | idited) |       |    |                           |    |        |  |  |  |
| Clinical development                    | \$ | 472                         | \$      | 1,599 | \$ | 1,136                     | \$ | 3,428  |  |  |  |
| Contract manufacturing                  |    | 402                         |         | 2,278 |    | 954                       |    | 5,406  |  |  |  |
| Discovery and non-clinical              |    | 18                          |         | 400   |    | 74                        |    | 825    |  |  |  |
| Personnel costs                         |    | 670                         |         | 1,403 |    | 1,928                     |    | 2,881  |  |  |  |
| Other allocated indirect costs          |    | 191                         |         | 325   |    | 597                       |    | 573    |  |  |  |
| Total research and development expenses | \$ | 1,753                       | \$      | 6,005 | \$ | 4,689                     | \$ | 13,113 |  |  |  |

We expect our research and development expenses to decrease in the near-term as we complete the clinical trials that have been ongoing and we begin to realize the effects of cost-reduction efforts in personnel costs, discovery and nonclinical expenses undertaken in 2022 and early 2023. Also, we expect our contract manufacturing costs in the near-term to be lower than in 2022 as we have completed the drug substance and drug product manufacturing activities for sotiga and APX601 that were underway in 2022, and we do not expect to initiate any new drug substance or drug product manufacturing runs in the near term. We anticipate the clinical development of sotiga, including potentially into a registration-enabling clinical trial, would involve significant costs.

#### General and Administrative Expenses

General and administrative expenses consist of salaries, benefits, and stock-based compensation expense for personnel in executive, operations, legal, human resources, finance and administrative functions, professional fees for legal, patent, consulting, accounting and audit services, and allocated expenses for technology and facilities. We expense general and administrative costs in the periods which they are incurred.

We expect increases in our general and administrative expenses as we anticipate transaction costs such as legal, audit, banker, and other consulting fees associated with the Pyxis Merger. Generally, we expect that our general and administrative expenses will increase as we anticipate incurring expenses related to compliance with the rules and regulations of the SEC, Sarbanes-Oxley Act and the listing standards of Nasdaq, additional corporate, director and officer insurance expenses, increased legal, audit and consulting fees and greater investor relations expenses.

#### Other Income, Net

Other income, net primarily relates to interest income on our cash and cash equivalents and short-term investments, change in fair value of derivative warrant liabilities, and fees related to our short-term investments.



### **Results of Operations**

#### Comparison of the Three and Six Months Ended June 30, 2023 and 2022

The following table presents our consolidated statement of operations data for the three and six months ended June 30, 2023 and 2022, and the dollar and percentage change between the two periods (in thousands):

|                            | Three Months Ended June 30,            |        |           |    |          |       | Six Months Ended June 30, |             |    |          |    |         |       |
|----------------------------|--|--------|-----------|----|----------|-------|---------------------------|-------------|----|----------|----|---------|-------|
|                            | 2023 2022 \$ Change % Change 2023 2022 |        | \$ Change |    | % Change |       |                           |             |    |          |    |         |       |
|                            | <br>(Unau                              | dited) | )         |    |          |       |                           | (Unaudited) |    |          |    |         |       |
| Operating expenses:        |  |        |           |    |          |       |                           |             |    |          |    |         |       |
| Research and development   | \$<br>1,753                            | \$     | 6,005     | \$ | (4,252)  | -71 % | 6 <b>\$</b>               | 4,689       | \$ | 13,113   | \$ | (8,424) | -64 % |
| General and administrative | 4,405                                  |        | 2,139     |    | 2,266    | 106 % | ó                         | 7,684       |    | 4,124    |    | 3,560   | 86 %  |
| Total operating expenses   | <br>6,158                              |        | 8,144     |    | (1,986)  | -24 % | 6                         | 12,373      |    | 17,237   |    | (4,864) | -28 % |
| Loss from operations       | <br>(6,158)                            | _      | (8,144)   |    | 1,986    | -24 % | <u>ó</u>                  | (12,373)    |    | (17,237) |    | 4,864   | -28 % |
| Other income, net          | 111                                    |        | 40        |    | 71       | 178 % | ó                         | 273         |    | 91       |    | 182     | 200 % |
| Net loss                   | \$<br>(6,047)                          | \$     | (8,104)   | \$ | 2,057    | -25 % | 6\$                       | (12,100)    | \$ | (17,146) | \$ | 5,046   | -29 % |

#### Costs and Expenses

#### Research and Development

Research and development expenses decreased by \$4.3 million, or 71%, to \$1.8 million for the three months ended June 30, 2023 from \$6.0 million for the three months ended June 30, 2022. The decrease primarily relates to a decrease of \$1.1 million in clinical development expenses, a decrease of \$1.9 million in contractual manufacturing, a decrease of \$0.7 million in personnel costs, and a decrease of \$0.6 million in discovery and other non-clinical expenses. The decreases are due to completion of the clinical trials, completion of manufacturing runs, and the impacts from our cost-reduction efforts.

Research and development expenses decreased by \$8.4 million, or 64%, to \$4.7 million for the six months ended June 30, 2023 from \$13.1 million for the six months ended June 30, 2022. The decrease primarily relates to a decrease of \$2.2 million in clinical development expenses, a decrease of \$4.4 million in contractual manufacturing, a decrease of \$1.0 million in personnel costs, and a decrease of \$0.8 million in discovery and other non-clinical expenses. The decreases are due to completion of the clinical trials, completion of manufacturing runs, and the impacts from our cost-reduction efforts.

#### General and Administrative

General and administrative expenses increased by \$2.3 million, or 106%, to \$4.4 million for the three months ended June 30, 2023 from \$2.1 million for the three months ended June 30, 2022. The increase is attributable to a \$1.5 million increase in transaction costs, a \$0.4 million increase in business insurance expenses, and a \$0.4 million increase in amortization of deferred financing costs.

General and administrative expenses increased by \$3.6 million, or 86%, to \$7.7 million for the six months ended June 30, 2023 from \$4.1 million for the six months ended June 30, 2022. The increase is attributable to a \$1.7 million increase in transaction costs associated with the Pyxis Merger, a \$0.7 million increase in business insurance expenses, a \$0.9 million increase in amortization of deferred financing costs, \$0.2 million increase in compensation, and \$0.1 million increase in severance.

#### Other Income, Net

Other income, net, increased by \$0.1 million for the three months ended June 30, 2023 as compared to the equivalent prior year period. The increase is primarily attributable to the increase in interest income.

Other income, net, increased by \$0.2 million for the six months ended June 30, 2023 as compared to the equivalent prior year period. The increase is primarily attributable to the increase in interest income.

#### Liquidity and Capital Resources

Since inception through June 30, 2023, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Our net losses were \$6.0 million and \$8.1 million for the three months ended June 30, 2023 and 2022, respectively, and \$12.1 million and \$17.1 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$188.9 million. We have funded our operations to date primarily through the issuance of stock as well as through proceeds from license agreements and borrowings under a debt arrangement. We will continue to be dependent upon equity and debt financings or collaboration-related revenue until we are able to generate positive cash flows from our operations. As of June 30, 2023, we had \$9.4 million in cash and cash equivalents and expect to fund our operations

into the fourth quarter of 2023 based on current operations without receiving any additional proceeds under our equity line agreement with Lincoln Park or any proceeds from any other potential financing or business development transactions. Our cash and cash equivalents consist primarily of bank deposits and money market funds. Based on our research and development activities and plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate the business effectively, which raises substantial doubt as to our ability to continue as a going concern.

### **Funding Requirements**

Our primary use of cash and cash equivalents is to fund operating expenses, which consist primarily of research and development expenditures related to our programs, and to a lesser extent, general and administrative expenditures. In connection with the restructuring, we have completed or otherwise paused enrollment in our clinical trials with the exception of the investigator-sponsored trial in patients with dedifferentiated liposarcoma and otherwise slowed or paused the advancement of our other product candidates in order to reduce our expenses as we pursued strategic alternatives and therefore expect our operating expenses to decrease in the near term. At this time, due to the inherently unpredictable nature of clinical development, we cannot reasonably estimate the costs we will incur and the timelines required to complete development, obtain marketing approval, and commercialize our current product candidate or any future product candidates. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or our current or any future license agreements that we may enter into or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast the timing and amounts of milestone, royalty and other revenue from licensing activities, which future product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future funding requirements will depend on many factors, including the following:

- the progress, timing, scope, results and costs of our clinical trials and preclinical studies for our product candidates, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs of obtaining clinical and commercial supplies and validating the commercial manufacturing process for sotigalimab and any other product candidates;
- our ability to successfully commercialize sotigalimab and any other product candidates;
- the cost, timing and outcomes of regulatory approvals;
- the extent to which we may acquire or in-license other product candidates and technologies;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreement;
- the extent to which we receive royalty payments though our current or any future partnership arrangements;
- our ability to attract, hire and retain qualified personnel;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- our activities to evaluate and pursue strategic alternatives.

As an early-stage biopharmaceutical company, we do not have any products approved for sale and have not generated any revenue from product sales. Due to the company being in the development stage, we have generated operating losses in all periods presented. We expect to incur losses in the future as we continue our research and development activities. Based on our research and development plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt as to our ability to continue as a going concern. There can be no assurance that such additional capital, whether in the form of debt or equity financing, will be sufficient or available and, if available, that such capital will be offered on terms and conditions acceptable to us.

In addition to the proceeds that we received from the private placement in January 2023, and if the contemplated merger with Pyxis Oncology is not completed, we may seek additional funds through the sale and issuance of shares of our common stock in



private or public offerings, other equity or debt financings, our equity line agreement with Lincoln Park, collaborations or partnerships with third parties, or other transactions to monetize assets, including our right to receive milestone payments and royalties under our out-license arrangements. We cannot assure that we will succeed in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or preclinical studies or research and development programs. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenditures associated with our current and planned research, development and manufacturing activities.

To the extent that we raise additional capital through strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our then-existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

## Cash Flows

The following table summarizes our cash flow data for the periods presented (in thousands):

|   | Six Months Ended<br>June 30, |      |          |  |  |  |
|---|------------------------------|------|----------|--|--|--|
|   | 2023                         | 2022 |          |  |  |  |
|   | <br>(Unaudited)              |      |          |  |  |  |
| Net cash used in operating activities               | \$<br>(9,763)                | \$   | (14,142) |  |  |  |
| Net cash provided by investing activities           | 2,150                        |      | 2,919    |  |  |  |
| Net cash provided by (used in) financing activities | 2,180                        |      | (576)    |  |  |  |

## Comparison of the Six Months Ended June 30, 2023 and 2022

#### **Operating Activities**

For the six months ended June 30, 2023, cash used in operating activities was \$9.8 million, which consisted of a net loss of \$12.1 million, partially offset by a net change of \$0.1 million in our net operating assets and liabilities and by non-cash charges of \$2.2 million. The change in our net operating assets and liabilities was primarily due to a \$1.2 million decrease in prepaid expenses and other current assets and a \$1.0 million increase in deferred revenue, partially offset by a decrease of \$2.0 million in accounts payable and accrued expenses and a decrease of \$0.1 million in lease liabilities. The non-cash charges are primarily comprised of \$0.8 million for stock-based compensation expense, \$0.9 million for amortization of deferred financing costs, \$0.4 million for expense from vesting of restricted stock awards, and \$0.1 million for non-cash lease expense.

For the six months ended June 30, 2022, cash used in operating activities was \$14.1 million, which consisted of a net loss of \$17.1 million, partially offset by non-cash charges of \$1.1 million and a net change of \$2.0 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of \$0.8 million for stock-based compensation expense, \$0.2 million for non-cash lease expense, and \$0.1 million for depreciation expense. The change in our net operating assets and liabilities was primarily due to an increase of \$1.2 million in accounts payable and accrued expenses and a \$1.0 million increase in deferred revenue, partially offset by \$0,2 million decrease in lease liabilities.

#### **Investing Activities**

For the six months ended June 30, 2023 and 2022, cash provided by investing activities was \$2.2 million and \$2.9 million, respectively. The change in cash flows from investing activities was principally from the timing of purchases and sales of marketable securities.

## **Financing Activities**

Net cash provided by financing activities for the six months ended June 30, 2023 was \$2.2 million and consisted primarily of the gross proceeds from the private offering, partially offset by the payments of transaction costs. Net cash used in financing activities for the six months ended June 30, 2022 was \$0.6 million for the payments of transaction costs.

#### **Contractual Obligations**

We lease our principal facility under a non-cancelable agreement with a lease term ending in September 2023.

In addition, we have entered into certain licensing agreements pursuant to which we will owe contingent payments if and when we sublicense or commercialize certain of our products, as well as certain collaboration agreements pursuant to which we may in the future owe certain amounts to our collaboration partners upon the achievement of certain milestones. Because these obligations are uncertain, and their timing and amount are not known, they are not included in the table above. These agreements are described in more detail in the section titled *"Licensing and Other Arrangements"* below.

We also enter into agreements in the normal course of business with contract research organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes, which are generally cancelable upon written notice. These obligations and commitments are also not included in the table above.

## Licensing and Other Arrangements

We have entered into license agreements and partnership agreements, including the agreement with Novartis described below, under which we have the right to receive, or are obligated to pay, certain contingent payments and royalties upon the achievement of specified milestones or net sales. With the exception of the agreement with Novartis described below, we do not anticipate any potential payments under these agreements in the foreseeable future, if at all.

#### Beovu® and Antibody Candidate Discovery and Development Agreement with Novartis

We have an agreement with Novartis relating to antibodies that Epitomics generated that target certain molecules which were used to develop antibody product candidates. Under the agreement, Novartis has a non-exclusive, irrevocable, worldwide, sublicensable, royalty-bearing and perpetual license to our rights in certain intellectual property to develop and commercialize those drug product candidates. Pursuant to the terms of the agreement, the upfront fee and all milestone payments due upon the achievement of certain pre-clinical and clinical development milestones have been paid. Novartis remains obligated to pay us a very low single-digit royalty on net sales of the Beovu (brolucizumab-dbll) product for therapeutic uses by Novartis, its affiliates or licensees.

In October 2019, Novartis' Beovu product was approved for commercial sale. Novartis has disputed its obligation to pay Beovu royalties to us and continues to pay us royalties under protest. As a result, we have determined that any sales-based royalty revenue that we may earn under this agreement is currently fully constrained. We have recorded the Beovu royalty proceeds as deferred revenue in the consolidated balance sheets. Deferred revenue totaled \$6.7 million and \$5.7 million as of June 30, 2023 and December 31, 2022, respectively.

#### **Clinical Collaborations**

We have entered into a number of collaboration arrangements for the clinical development of sotigalimab with companies and academic and nonprofit institutions. These arrangements specify whether we or the collaborator bears the cost of the clinical trials, and in the case of combination therapies, typically the collaborators provide the supply of such drug products while we supply sotigalimab. Our applicable share of the costs of these clinical collaborations are reflected as research and development expenses.

Upon achievement of certain regulatory and clinical milestones related to the development of sotigalimab in pancreatic cancer, we will be obligated to pay an aggregate of up to \$9.5 million in cash and shares of common stock. Because we are not currently advancing the development of sotiga in pancreatic cancer, none of these milestones were probable as of June 30, 2023, and no amounts have been recognized.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future significant effect on our financial condition, results of operations, liquidity or cash flows.

#### **Major Vendors**

We had one major vendor that accounted for approximately 18.2% and 36.1% of the research and development expenses for the three months ended June 30, 2023 and 2022, respectively and approximately 16.2% and 39.4% of the research and development expenses for the six months ended June 30, 2023 and 2022, respectively. The same vendor also accounted for approximately 8.0% and 24.8% of the total accounts payable and accrued liabilities as of June 30, 2023 and December 31, 2022, respectively. Moreover, there



is a second vendor that accounted for approximately 41.1% and 33.6% of the total accounts payable and accrued liabilities as of June 30, 2023 and December 31, 2022, respectively, but we did not incur any expenses with this vendor during the three and six months ended June 30, 2023 and 2022.

We had a third vendor that accounted for approximately 26.7% and 19.7% of the general and administrative expenses for the three and six months ended June 30, 2023, respectively. This same vendor accounted for approximately 15.4% of the total accounts payable and accrued liabilities as of June 30, 2023.

#### **Emerging Growth Company**

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until those standards would otherwise apply to private companies. The JOBS Act provides that an emerging growth companies but any such election to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company, which is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

#### **Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in accordance with GAAP. The preparation of the consolidated financial statements in conformity with GAAP requires our management to make a number of estimates and assumptions relating to the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the period. We evaluate our significant estimates on an ongoing basis, including estimates related to accruals for research and development costs, stock-based compensation and uncertain tax positions. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

We believe that the accounting policies described below involve a significant degree of judgment and complexity. Accordingly, we believe these are the most critical to aid in fully understanding and evaluating our financial condition and results of operations. For further information, see Note 2, *Summary of Significant Accounting Policies*, to the consolidated financial statements included elsewhere in this Form 10-Q.

#### **Revenue Recognition**

Under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, we recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. We have not commenced sales of our product candidates and do not have a product approved for sale as of June 30, 2023.

We have other license agreements with third parties, under which we may also earn contingent fees including milestone payments based on counterparty performance and royalties on sales. We recognize milestone payments as revenue once the underlying events are probable of being met and there is not a significant risk of reversal. We recognize sales-based royalties as revenue when the underlying sales occur.

For more information on revenue recognition, see Note 2, *Summary of Significant Accounting Policies*, to the consolidated financial statements included elsewhere in this Form 10-Q.

#### **Research and Development Expenses**

We expense research and development costs as incurred. Research and development consist of costs incurred for the development of sotiga, our lead product candidate, as well as APX601 and other product candidates. Research and development costs consist primarily of external costs related to clinical development, contract manufacturing, preclinical development and discovery as



well as personnel costs and allocated overhead, such as rent, equipment, depreciation and utilities. Personnel costs consist of salaries, employee benefits and stock-based compensation.

We estimate external research and development expenses based on the services performed, pursuant to contracts with commercial and academic institutions that conduct and manage research and development services on our behalf. We record the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued liabilities in the consolidated balance sheets. These costs are a component of our research and development expenses. We accrue these costs based on factors such as the number of subject visits, the number of active patients, the number of patients enrolled, and estimates of the work completed and other measures in accordance with agreements established with our third-party service providers. As actual costs become known, we adjust our accrued liabilities. We have not experienced any significant differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expenses in future periods. Changes in these estimates that result in significant changes to our accruals could significantly affect our results of operations.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development are capitalized and then expensed as the related goods are delivered or the services are performed. We evaluate such payments for current or long-term classification based on when they will be realized.

#### Stock-based Compensation

Stock-based compensation, inclusive of stock options with only a service condition, and stock options with performance conditions, are awarded to our officers, directors, employees, and certain non-employees, in addition to the estimated shares of common stock to be purchased under our Employee Stock Purchase Plan (the "ESPP").

We account for stock-based compensation in accordance with ASC Topic 718, "*Compensation—Stock Compensation.*" We measure all equity awards granted to employees and non-employees based on the estimated grant date fair value. For awards subject to service-based vesting conditions, we recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting term. For awards subject to performance-based vesting conditions, we recognize stock-based compensation expense using the accelerated attribution method when it is probable that the performance condition will be achieved. We recognize forfeitures as they occur.

We calculate the fair value of stock options using the Black-Scholes option pricing model and recognize expense using the straight-line attribution approach. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including the fair value of our common stock, the expected term of the awards, expected stock price volatility, the risk-free interest rate for a period that approximates the expected term of the awards and our expected dividend yield.

*Expected Term*—We determine the expected life of options granted using the "simplified" method. Under this approach, we presume the expected terms to be the mid-point between the weighted-average vesting term and the contractual term of the option. The simplified method makes the assumption that the award recipient will exercise share options evenly over the period when the share options are vested and ending on the date when the share options would expire.

*Risk-Free Interest Rate*—We base the risk-free interest rate from the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected term.

*Expected Volatility*—Because our stock is recently traded in an active market, we calculate volatility by using the historical volatilities of the common stock of comparable publicly traded companies. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

*Expected Dividends*—We have never paid cash dividends on our common stock and do not have plans to pay cash dividends in the future. Therefore, we use an expected dividend yield of zero.

As of June 30, 2023, the unrecognized stock-based compensation expense related to equity awards was \$3.1 million and is expected to be recognized as expense over a weighted-average period of approximately 2.2 years.

For more information, see Note 8, Stock-Based Compensation, to the consolidated financial statements included elsewhere in this Form 10-Q.



## **New Accounting Pronouncements**

See Note 2, Summary of Significant Accounting Policies, to our consolidated financial statements included elsewhere in this Form 10-Q.

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

We are exposed to certain credit and interest rate risks as part of our ongoing business operations.

#### Credit Risk

We are exposed to credit risk on our money market funds. Investments that potentially subject us to credit risk consist principally of cash and cash equivalents. We place our cash and cash equivalents with financial institutions with high credit standing and our excess cash in marketable investment grade securities.

### **Interest Rate Risk**

We had cash, cash equivalents and short-term investments of \$9.4 million and \$16.8 million as of June 30, 2023 and December 31, 2022, respectively. The primary goals of our investment policy are liquidity and capital preservation. We do not enter into investments for trading or speculative purposes. We believe that we do not have any significant exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents. Declines in interest rates, however, would reduce future investment income. A hypothetical 1.00% (100 basis points) increase in interest rates would not have materially impacted the fair value of our short-term investments as of June 30, 2023 and December 31, 2022. If overall interest rates had increased or decreased by 1.00% (100 basis points), our interest income would not have been materially affected during the year ended December 31, 2022 or six months ended June 30, 2023.

#### Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contracts. We do not believe that inflation has had a significant effect on our financial results during the periods presented. However, to the extent that the inflation the United States has recently experienced results in rising interest rates and has other adverse effects on the market, it may adversely affect our future consolidated financial condition and results of operations.

#### Item 4. Controls and Procedures.

### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period ended June 30, 2023, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer have concluded that during the period covered by this report, our disclosure controls and procedures were effective as of June 30, 2023 to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized, and reported within the time periods specified in U.S. Securities and Exchange Commission ("SEC") rules and forms, and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

### Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the three months ended June 30, 2023 covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II—OTHER INFORMATION

#### Item 1. Legal Proceedings.

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

#### Item 1A. Risk Factors.

An investment in our common stock involves risks. Prior to making a decision about investing in our common stock, you should consider carefully the risks together with all of the other information contained in this report, including any risks described below. Each of the referenced risks and uncertainties could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities. Additional risks not known to us or that we believe are immaterial may also adversely affect our business, operating results and financial condition and the value of an investment in our securities. "Apexigen," "the Company," "we," "us" or "our" refers to Legacy Apexigen prior to the consummation of the Brookline Merger and to Apexigen following the Brookline Merger.

#### **Summary Risk Factors**

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company, as more fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

- The failure to complete the Pyxis Merger in a timely manner, or at all, may adversely affect the business and financial results of Pyxis Oncology and us and each of our respective stock prices.
- The Exchange Ratio is fixed and will not be adjusted in the event of any change in the stock prices of either Pyxis Oncology or us.
- Uncertainty about the Pyxis Merger may adversely affect the respective business and stock price of Pyxis Oncology and us, whether or not the Pyxis Merger is completed.
- Our activities to evaluate and pursue strategic alternatives may not be successful.
- If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that we will need to reserve for commitments and contingent liabilities.
- We are substantially dependent on our remaining employees to facilitate the consummation of a strategic transaction. We could lose such key employees as a result of the prospects for the company.
- We have incurred net losses since inception and expect to continue to incur significant net losses for the foreseeable future. In addition, we may be unable to continue as a going concern.
- We will require substantial additional capital to finance operations. If we are unable to raise such capital when needed or on acceptable terms, we may be forced to delay, reduce, and/or eliminate one or more research and drug development programs or future commercialization efforts.
- We are in the early stages of clinical drug development and have a limited operating history and no products approved for commercial sale.
- We are dependent on the success of our product candidates, including our lead product candidate, sotigalimab, which is currently in multiple clinical trials.
- The clinical trials of our current and any future product candidates may not demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise be timely conducted or produce positive results.
- If our competitors develop and market products that are more effective, safer, or less expensive than our product candidates, we will be negatively impacted.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.



- The regulatory approval processes of the Food and Drug Administration, European Medicines Agency, and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- If we are unable to obtain, maintain, enforce, or protect our intellectual property rights in any products we develop or in our technology, if the scope of the intellectual property protection obtained is not sufficiently broad, or if we infringe the intellectual property rights of others, third parties could develop and commercialize products and technology similar or identical to ours, we could be prevented from commercializing our products and we may not be able to compete effectively in our markets.

### **Risks Related to the Proposed Pyxis Merger**

## The failure to complete the Pyxis Merger in a timely manner, or at all, may adversely affect the business and financial results of Pyxis Oncology and us and each of our respective stock prices.

Each of Pyxis Oncology's and our obligations to consummate the Pyxis Merger are subject to the satisfaction or waiver of certain conditions, including, among other things, (1) adoption of the Pyxis Merger Agreement by our stockholders, (2) the absence of any order or legal restraint that prevents the consummation of the Pyxis Merger, and (3) the approval for listing of the shares of Pyxis Oncology common stock to be issued in connection with the Pyxis Merger on Nasdaq and the effectiveness of a registration statement with respect to such Pyxis Oncology common stock. Each party's obligation to consummate the Pyxis Merger is also subject to other specified customary conditions, including the representations and warranties of the other party being true and correct as of the date of the Pyxis Merger Agreement and as of the closing date of the Pyxis Merger, generally subject to an overall material adverse effect qualification, and the performance in all material respects by the other party of its obligations under the Pyxis Merger Agreement required to be performed on or prior to the date of the closing of the Pyxis Merger.

#### The Exchange Ratio is fixed and will not be adjusted in the event of any change in the stock prices of either Pyxis Oncology or us.

Upon closing of the Pyxis Merger, each share of our common stock will be converted into the right to receive the Exchange Ratio of 0.1725 of a share of Pyxis Oncology common stock. This Exchange Ratio is fixed in the Pyxis Merger Agreement and will not be adjusted for changes in the market price of either Pyxis Oncology common stock or our common stock. Because the Exchange Ratio will not be adjusted for changes in the market price of Pyxis Oncology common stock, the market value of the shares of Pyxis Oncology common stock that holders of our common stock will be entitled to receive at the effective time of the Pyxis Merger may vary significantly from the market value of the shares of Pyxis Oncology common stock would have received if the Pyxis Merger had been completed on any other date, including the date of the Pyxis Merger Agreement. In addition, Pyxis Oncology will issue a number of shares of Pyxis Oncology common stock in connection with the Pyxis Merger based on the number of shares of our common stock, including as of the effective time of the Pyxis Merger, which may result in fluctuations in the market price of Pyxis Oncology common stock, including a stock price decline. The amount of shares of Pyxis Oncology common stock as of the effective time of the Pyxis Merger or their relative price.

The Pyxis Merger Agreement does not provide for any termination right by either Pyxis Oncology or us solely based on changes in the price or trading volume of Pyxis Oncology common stock or our common stock.

Because the Pyxis Merger will be completed after the date of our special meeting of stockholders, at the time of our special meeting of stockholders, you will not know the exact market value of the Pyxis Oncology common stock that our stockholders and certain other of our equityholders will receive upon completion of the Pyxis Merger.

## Uncertainty about the Pyxis Merger may adversely affect the respective business and stock price of Pyxis Oncology and us, whether or not the Pyxis Merger is completed.

Each of Pyxis Oncology and we are subject to risks in connection with the announcement and pendency of the Pyxis Merger, including the pendency and outcome of any legal proceedings against Pyxis Oncology and us, each of our respective directors and others relating to the Pyxis Merger and the risks from possibly foregoing opportunities Pyxis Oncology and we might otherwise pursue absent the proposed Pyxis Merger. Furthermore, uncertainties about the Pyxis Merger may cause current and prospective employees of Pyxis Oncology and us to experience uncertainty about their future with their respective companies. These uncertainties may impair Pyxis Oncology's and our ability to retain, recruit or motivate key management and other personnel.

In addition, in response to the announcement of the proposed Pyxis Merger, Pyxis Oncology's and our existing or prospective suppliers or collaboration partners may:

delay, defer or cease providing goods or services to Pyxis Oncology and us;



- delay or defer other decisions concerning Pyxis Oncology and us, or refuse to extend credit terms to Pyxis Oncology and us;
- cease further joint development activities; or
- otherwise seek to change the terms on which they do business with Pyxis Oncology and us.

While Pyxis Oncology and we are attempting to address these risks, each of our respective existing and prospective customers, suppliers or collaboration partners may be reluctant to purchase Pyxis Oncology's and our products, supply Pyxis Oncology and us with goods and services or continue collaborations due to the potential uncertainty about the direction of Pyxis Oncology's and our product offerings and the support and service of Pyxis Oncology's and our products after the completion of the Pyxis Merger.

#### While the Pyxis Merger is pending, we are subject to contractual restrictions that could harm our business, operating results and stock price.

The Pyxis Merger Agreement includes restrictions on the conduct of our business prior to the completion of the Pyxis Merger, generally requiring us to conduct our business in the ordinary course, consistent with past practice, and restricting us from taking certain specified actions absent Pyxis Oncology's prior written consent. These and other obligations in the Pyxis Merger Agreement may delay or prevent us from or limit our ability to respond effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management and our board of directors think they may be advisable. These restrictions could adversely impact our business, operating results and stock price and our perceived acquisition value, regardless of whether the Pyxis Merger is completed.

## The Pyxis Merger Agreement limits our ability to pursue alternative transactions which could deter a third party from proposing an alternative transaction.

The Pyxis Merger Agreement contains provisions that, subject to certain exceptions, limit, among other things, our ability to participate in any negotiations or discussions regarding, or, knowingly, with the intention to encourage or facilitate, furnish any nonpublic information in response to inquiries with respect to an alternative transaction. It is possible that these or other provisions in the Pyxis Merger Agreement might discourage a potential competing acquirer that might have an interest in acquiring all or a significant part of the outstanding shares of our common stock from considering or proposing an acquisition, or might result in a potential competing acquirer proposing to pay a lower per share price to acquire our common stock than it might otherwise have proposed to pay.

#### The Pyxis Merger will involve substantial costs.

Pyxis Oncology and we have incurred and expect to continue to incur substantial costs and expenses relating to the Pyxis Merger and the issuance of Pyxis Oncology common stock in connection with the Pyxis Merger, including, as applicable, fees and expenses payable to financial advisors, other professional fees and expenses, insurance premium costs, SEC filing fees, printing and mailing costs and other transaction-related costs, fees and expenses. Pyxis Oncology also will incur significant transaction fees and costs in connection with its formulating and implementing integration plans with respect to the two companies. Pyxis Oncology continues to assess the magnitude of these costs, and additional unanticipated costs may be incurred in connection with the Pyxis Merger and the integration of the two companies' businesses. In addition, if the Pyxis Merger is not completed, Pyxis Oncology and we will have incurred substantial expenses for which no ultimate benefit will have been received by either company.

## The fairness opinion obtained by our board of directors from our financial advisor will not be updated to reflect changes in circumstances between signing the Pyxis Merger Agreement and the completion of the Pyxis Merger.

Our board of directors has not obtained an updated fairness opinion as of the date of this quarterly report from Ladenburg Thalmann & Co. Inc. ("Ladenburg"), our financial advisor. Changes in the operations and prospects of Pyxis Oncology or us, general market and economic conditions, and other factors that may be beyond the control of Pyxis Oncology and us and upon which the fairness opinion was based, may alter the value of Pyxis Oncology or us or the price of Pyxis Oncology common stock or our common stock by the time the Pyxis Merger is completed.

The fairness opinion does not speak as of the time the Pyxis Merger will be completed or as of any date other than the date of such opinion. We do not anticipate asking Ladenburg to update its fairness opinion.

## Certain of our directors and executive officers may have interests in the Pyxis Merger that are or were different from, or in conflict with or in addition to, those of our stockholders generally.

In considering whether to approve the proposals at our special meeting of stockholders, our stockholders should recognize that our directors and officers have interests in the Pyxis Merger that may differ from, or that are in addition to, their interests as our



stockholders. Our board of directors was aware of these interests at the time it approved the Pyxis Merger Agreement. These interests may cause our directors and officers to view the Pyxis Merger differently from how you may view it as a stockholder.

#### Holders of our common stock will not be entitled to appraisal rights in the Pyxis Merger.

Appraisal rights are statutory rights that, if applicable under law, enable stockholders to dissent from an extraordinary transaction, such as a merger, and to demand that the corporation pay the fair value for their shares as determined by a court in a judicial proceeding instead of receiving the consideration offered to shareholders in connection with the extraordinary transaction.

Under Section 262(b) of the DGCL, stockholders do not have appraisal rights if the shares of stock they hold, as of the record date for determination of stockholders entitled to vote at the meeting of shareholders to act upon a merger, are either (i) listed on a national securities exchange or (ii) held of record by more than 2,000 holders, unless the stockholders are required by the terms of the merger agreement to receive in exchange for their shares in the merger anything other than shares of stock of the surviving or resulting corporation (or depositary receipts in respect thereof), or of any other corporation that is publicly listed or held by more than 2,000 holders of record, cash in lieu of fractional shares or fractional depositary receipts described above or any combination of the foregoing. Because our stockholders will receive only shares of Pyxis Oncology common stock which will be listed on Nasdaq and cash in lieu of any fractional shares, Apexigen stockholders will not have any appraisal rights.

#### Pyxis Oncology or we may waive one or more of the closing conditions to the Pyxis Merger without re-soliciting approval from our stockholders.

To the extent permitted by law, Pyxis Oncology or we may determine to waive, in whole or part, one or more of the conditions to their respective obligations to consummate the Pyxis Merger. We expect to evaluate the materiality of any waiver and its effect on our stockholders in light of the facts and circumstances at the time to determine whether any amendment of this proxy statement/prospectus or any re-solicitation of proxies is required in light of such waiver. Any determination as to whether to waive any condition to the consummation of the Pyxis Merger, and as to whether to re-solicit approval from our stockholders, will be made by Pyxis Oncology and us at the time of such waiver based on the facts and circumstances as they exist at that time.

## After the Pyxis Merger, our stockholders will have a significantly lower ownership and voting interest in Pyxis Oncology than they currently have in us and will exercise less influence over management and policies of the combined company.

Upon completion of the Pyxis Merger and based on 39,414,292 shares of Pyxis Oncology common stock and 24,850,082 shares of our common stock outstanding as of June 28, 2023, it is expected that Pyxis Oncology stockholders and certain other equity holders will own approximately 90% of the outstanding common stock of the combined company and our stockholders and certain other equityholders will own approximately 10% of the outstanding common stock of the combined company. Consequently, our former stockholders will have less influence over the management and policies of the combined company than they currently have over our management and policies.

## We and Pyxis Oncology may be targets of securities class action and derivative lawsuits which could result in substantial costs and may delay or prevent the Pyxis Merger from being completed.

Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. Even if the lawsuits are without merit, defending against these claims could result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on Pyxis Oncology's and our respective liquidity and financial condition. Additionally, if a plaintiff is successful in obtaining an injunction prohibiting completion of the Pyxis Merger, then that injunction may delay or prevent the Pyxis Merger from being completed, or from being completed within the expected timeframe, which may adversely affect Pyxis Oncology's and our respective business, financial position and results of operations.

## The following risk factors do not take into account the proposed Pyxis Merger and assume that we remain a stand-alone company except as otherwise noted.

#### **Risks Related to Our Strategic Alternatives Process**

#### Our activities to evaluate and pursue strategic alternatives may not succeed.

In February 2023, we announced that we would explore the potential for an acquisition, company sale, merger, divestiture of assets, licensing, or other strategic transactions. We engaged Ladenburg Thalmann as our strategic advisory firm to help explore available strategic alternatives for the company.

We have significantly reduced our research and development activities to reduce operating expenses while we evaluated these opportunities. We expect to continue to devote significant time and resources as we complete the planned Pyxis Merger. In addition,



the planned Pyxis Merger requires the approval of our stockholders, which we may not obtain. Further, any strategic transaction that we ultimately complete may not deliver the anticipated benefits or enhance stockholder value.

Any strategic transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- higher than anticipated transaction or integration costs;
- difficulty and cost in integrating the operations and personnel of any entity with which we may combine;
- exposure to unknown liabilities;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- write downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- impairment of relationships with key suppliers or vendors due to changes in management and ownership; and
- the inability to retain our key employees or our other service providers.

Accordingly, there can be no assurance that we will undertake or successfully complete any strategic transactions of the nature described above, including the Pyxis Merger, and any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, financial condition and prospects.

## If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of the Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that we will need to reserve for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic alternative will result in a successfully consummated transaction. If we do not complete a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of the Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution will continue to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the Company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations; (ii) obligations under our employment, retention and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, we may need to reserve a portion of our assets pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of the Company. If we pursue a dissolution and liquidation, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or windi

#### Risks Related to Our Business, Financial Condition, and Need for Additional Capital

## We have incurred net losses since inception and expect to continue to incur significant net losses for the foreseeable future. In addition, we may be unable to continue as a going concern.

We have incurred net losses since inception, have not generated any significant revenue to date, and financed our operations prior to the Brookline Merger primarily through the issuance of convertible preferred stock, proceeds from collaborative research and development and out-license agreements, and borrowings under a debt arrangement. Our net loss was \$6.0 million and \$8.1 million for the three months ended June 30, 2023 and 2022, respectively, and \$12.1 million and \$17.1 million for the six months ended June 30, 2023 and 2022, respectively.

As of June 30, 2023, we had an accumulated deficit of \$188.9 million. To date, we have devoted substantially all of our resources and efforts to research and development. Our clinical-stage pipeline currently consists of multiple product candidates, including our lead product candidate, sotigalimab, and our other internal programs are in preclinical or research development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products. In addition, for certain of our licensees from whom we are entitled to receive royalty payments if they successfully develop and commercialize any products covered by licenses we have with them, there is no guarantee that their product development and commercialization will lead to any such payments even if any such product candidates receive regulatory approval for commercial sale, including Beovu (brolucizumab-dbll), which is commercialized by Novartis, for which we have received sales-based royalties that are currently fully constrained and recorded as deferred revenue on our consolidated balance sheet, as discussed below.

In connection with the Brookline Merger, we raised approximately \$19.0 million of gross proceeds. We incurred approximately \$9.2 million in transaction costs relating to the Brookline Merger, consisting of banking, legal, and other professional fees. The total net cash proceeds to us were approximately \$8.9 million after we paid off the Extension and Working Capital Notes that totaled \$0.9 million. In addition, we raised approximately \$2.8 million of gross proceeds from the private placement transaction in January 2023. We incurred approximately \$0.7 million in transaction costs relating to the private placement agent, legal, and other professional fees.

Our condensed consolidated financial statements for the three and six months ended June 30, 2023 and 2022, included elsewhere in this Quarterly Report on Form 10-Q have been prepared assuming we will continue as a going concern. As a development stage company, we expect to incur significant and increasing losses until regulatory approval is granted for sotigalimab, our lead product candidate. Regulatory approval is not guaranteed and may never be obtained. Based on our research and development activities and plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate the business effectively, which raises substantial doubt about our ability to continue as a going concern. If we do not receive proceeds under our equity line or other potential financing or business development transactions, we anticipate that our current cash position would only be sufficient to fund our operations into the fourth quarter of 2023 based on current operations.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our expected future losses will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

## We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce, and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for sotigalimab and our other product candidates. In order to support the advancement of the sotigalimab clinical development program, we are actively seeking a global development and commercialization collaboration partner for sotigalimab. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing, and distribution. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, or to enter into a collaboration to support the advancement of the sotigalimab development program, we may be forced to delay, reduce, and/or eliminate one or more of our research and drug development programs or future commercialization efforts. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.



We plan to continue to use our cash on hand to fund our development of sotigalimab, and for working capital and other general corporate purposes. This may include additional research, hiring additional personnel, capital expenditures, and the costs of operating as a public company. Advancing the development of our current and any future product candidates will require a significant amount of capital. Our current cash and cash equivalents are not sufficient to fund all of the actions that are necessary to complete the development of sotigalimab or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, sale of shares of our common stock through utilization of our equity line with Lincoln Park, debt financings, partnership, collaborations, and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. In addition, there are certain conditions and limitations on our ability to utilize our \$50,000,000 equity line with Lincoln Park. We are required to satisfy various conditions in order to be able to initiate additional purchases by Lincoln Park under the equity line. Once such conditions are satisfied, the Lincoln Park equity line purchases are subject to volume limitations tied to periodic market prices, ownership limitations limiting Lincoln Park from owning more than 4.99% of our common stock, and other limitations as specified in the equity line agreement. If any of these conditions are not satisfied or limitations are in effect, we may not be able to fully utilize the Lincoln Park equity line, which would have an adverse impact on our ability to satisfy our capital needs and could materially adversely impact our business. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

## We are in the early stages of clinical drug development and have a limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are an early clinical-stage biopharmaceutical company with a limited operating history. Apexigen was incorporated and commenced operations in 2010 following a spin-out transaction from its parent company. We have no products approved for commercial sale and have not generated any revenue from commercial product sales. Our operations to date have been limited to performing research and development activities in support of our product development and licensing efforts, hiring personnel, raising capital to support and expand such activities, providing general and administrative support for these operations, developing potential product candidates, conducting preclinical studies and clinical trials, including clinical trials of sotigalimab, our lead product candidate, and our other wholly owned product candidates, and entering into, and performing our obligations under, licensing arrangements that have resulted in additional product candidates in clinical development or commercialization by our licensees. Other than sotigalimab, all of our wholly owned programs are in preclinical or research development. We have not yet demonstrated our ability to successfully complete any large-scale pivotal clinical trials, obtain marketing approvals, manufacture a drug on a commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities. In addition, only one of our licensees has obtained marketing approvals for product candidates we have out-licensed. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also would need to transition from a company with a research and development focus to a company capable of supporting commercial activities after approval of any of our product candidates. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

#### Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from commercial sales of any products. We have no products approved for commercial sale and we do not anticipate generating any revenue from product sales unless and until sometime after we have successfully completed clinical development and received marketing approval for the commercial sale of a product candidate, if ever. In addition, we may not receive significant amounts of royalty revenue, if any, from our licensees for their product candidates if and when such candidates receive regulatory approval for commercial sale and are commercialized, including Beovu, which is commercialized by Novartis, for which we have received sales-based royalties that are currently fully constrained and recorded as deferred revenue on our consolidated balance sheet as discussed below. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- raising substantial additional capital to finance our operations;
- negotiating favorable terms in any partnership, collaboration, licensing, or other arrangements that may be necessary to develop, manufacture, or commercialize our product candidates;



- successful and timely completion of preclinical and clinical development of current and any future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for current and any future product candidates for which we successfully complete clinical development;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for current and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;
- successful launch of commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more partners or collaborators;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance of current and any future product candidates as viable treatment options by patients, the medical community, and third-party payors;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring, and developing new product candidates;
- obtaining and maintaining patent protection, regulatory exclusivity, and other intellectual property-related protection, both in the United States and internationally;
- enforcing and defending our rights in our intellectual property portfolio, including our licensed intellectual property; and
- attracting, hiring, and retaining qualified personnel.

We may never achieve our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, or continue our operations.

#### Risks Related to the Discovery, Development, and Commercialization of Our Product Candidates

#### We depend on the success of our product candidates, including our lead product candidate, sotigalimab, which is currently in multiple clinical trials. If we are unable to obtain approval for and commercialize our product candidates for one or more indications in a timely manner, our business will be materially harmed.

Our success depends on our or our partners' or licensees' ability to timely complete clinical trials and obtain marketing approval for, and then successfully commercialize, our product candidates, including our lead product candidate, sotigalimab, for one or more indications. Our product candidates are in the early stages of development and we are investing the majority of our efforts and financial resources in the research and development of sotigalimab for multiple indications, both directly through our own efforts and indirectly through clinical collaboration arrangements, including investigator- and cooperative group-sponsored trials ("ISTs"). Our product candidates will require additional clinical development, preclinical and manufacturing activities, marketing approval from government regulators, substantial investment, and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any product candidates, in a jurisdiction before receiving marketing approval from the relevant regulatory authority, including, for example, the Food and Drug Administration ("FDA") for marketing in the United States and the European Medicines Agency ("EMA") for marketing in the European Union, and we may never receive such marketing approvals.

The success of our product candidates will depend on numerous factors, including the following:

• raising additional funds, or entering into collaborations, necessary to complete the clinical development of and to commercialize of our product candidates;



- successful and timely completion of our ongoing clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers;
- the maintenance of existing or the establishment of new scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community, and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, including trial design, implementation, and timely provision of data in our collaboration based clinical trials and ISTs; potential threats to our intellectual property rights; and the manufacturing, marketing, distribution, and sales efforts of any future collaborator. If we are unable to achieve one or more of the objectives set forth above, our business will be materially harmed.

## Our clinical trials may reveal serious adverse events, toxicities, or other side effects of our current and any future product candidates that result in a safety profile that could inhibit regulatory approval or market acceptance of our product candidates.

In order to obtain marketing approval for our current or any future product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials, or have unexpected characteristics, we may need to interrupt, delay, or abandon their development or limit 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.

Although we have conducted various preclinical studies and have data from various early-stage clinical trials, we do not know the predictive value of these studies and trials for our future clinical trials, and we cannot guarantee that any positive results in preclinical studies or previous clinical trials will successfully translate to patients in our future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical testing or previous clinical trials, and many product candidates fail in clinical trials despite promising preclinical or early-stage clinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

While we believe that sotigalimab has been reasonably well tolerated in our clinical trials, subjects have experienced adverse events that have been considered treatment-related. Some of the more common adverse events included fever, chills, fatigue, asthenia, nausea, vomiting, pruritus, abnormal liver function/gamma gamma-glutamyl transferase/alkaline phosphatase tests, decreased appetite, rash, headache, diarrhea, infusion-related reactions, and cytokine release syndrome ("CRS"). The majority of these events were mild/moderate in severity, responded to symptomatic treatment and/or were transient and resolved with time.

Serious, including sometimes fatal, adverse events ("SAEs") have been reported in clinical studies with sotigalimab. The majority of these SAEs were considered unrelated to sotigalimab by the investigators. Some SAEs were considered at least possibly related to sotigalimab as well as possibly to other therapies it was combined with.

These possibly related events have included infusion-related reactions, CRS, elevated liver enzymes, bilirubin, fever, and colitis. Less frequent related SAEs reported in one patient each have included kidney injury, hepatic failure, bleeding, immune-mediated encephalitis, myositis, optic neuritis. Many of these SAEs were also considered possibly related to the chemotherapy, radiation or anti-PD(L)1 agent that were used in combination or were assessed as not related to sotigalimab after a safety review by the trial sponsor.

Subjects experienced numerous other SAEs that have been determined to be caused by their health condition or the side effects from other components of the treatment regimens, and not or unlikely related to sotigalimab. Given the high mortality rates of the cancers for which we are initially pursuing development, in particular melanoma, esophageal and gastroesophageal junction ("GEJ") cancers, sarcoma, and ovarian cancer, and the pretreated nature of many patients in our completed, ongoing and planned clinical trials of sotigalimab, a number of these subjects have died as a result of their cancer or from direct side effects of surgery and other treatment regimens for their cancer. For example, in our clinical trial for esophageal and GEJ cancers, sotigalimab is combined with standard of care neoadjuvant chemotherapy, radiation and surgery. These standard of care treatments alone are associated with significant toxicities including fatal outcomes, and in this study, complications of surgery have resulted in the death of a patient.

We expect that subjects in our ongoing and planned clinical trials for our product candidates may in the future suffer adverse effects ("AEs"), SAEs or other side effects, including those not observed in our preclinical studies or previous clinical trials. Results of these 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 result in the delay, suspension, or termination of clinical trials by us or the FDA, EMA or comparable foreign regulatory authority for a number of reasons. Additionally, a number of the subjects in these clinical trials are expected to die during a trial due to the cancers they suffer and any of the treatment regimens they may have previously experienced, which could impact the development of our product candidates. If we elect or are required to delay, suspend, or terminate any clinical trial, the commercial prospects of our product candidates will be harmed and our ability to generate product revenue from this product candidate will be delayed or eliminated. SAEs observed in clinical trials could hinder or prevent market acceptance of our drug candidates. Any of these occurrences may harm our business, prospects, financial condition, and results of operations significantly.

Even in circumstances in which we do not believe that an AE is related to our product candidates, the investigation into the circumstances of such AE may be time-consuming or inconclusive. In particular, patients may face serious medical issues associated with the underlying cancer indications that our product candidates target, as well as AEs from toxicities and other complications related to other study drugs administered alongside or in combination with our product candidates in clinical trials. For example, some of our clinical trials involve combination therapies of our product candidate with other cancer therapies, such as standard-of-care chemotherapy, chemoradiation or anti-PD-(L)1 agents. In these trials, it is difficult to ascertain whether treatment-related AEs are attributable to our product candidates or to the other agents, and the combination of therapies may have a complicating multiplier effect on such AEs that cannot be determined. As a result, while not directly associated with our product candidates, there are attendant risks with the space in which our product candidates operate, and any related investigations may interrupt our development and commercialization efforts, delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain.

If further SAEs or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may discontinue treatment or withdraw from our trials or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other applicable regulatory authorities or an Institutional Review Board ("IRB")/Ethics Committee may suspend 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. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude a drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product, or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical testing.

## If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not initiate, continue or complete clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA, or comparable foreign regulatory authorities.

Patient enrollment is a significant factor in the timing of clinical trials, and our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of, our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the ability to monitor patients adequately during and after treatment;
- competing ongoing clinical trials for the same indications as our product candidates;
- proximity and availability of clinical trial sites for prospective patients;
- whether we become subject to a partial or full clinical hold on any of our clinical trials; and
- continued enrollment of prospective patients by clinical trial sites, including delays due to pandemics, wars etc. that can impact patient willingness to participate and travel for investigative therapy and reductions in clinical trial site staff and services.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more of our clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates.

## The clinical trials of our current and any future product candidates may not demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise be timely conducted or produce positive results.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. In addition, in our clinical trials of sotigalimab that are in combination with other available therapies, the results may be uncertain as to the efficacy of the sotigalimab combination when compared to the efficacy of other therapies that are being applied in the trial.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- delays in reaching, or the inability to reach, agreement on acceptable terms with prospective contract research organizations ("CROs"), clinical trial sites, laboratory service providers, companion diagnostic development partners, contract manufacturing organizations, or CMOs, and other service providers we may engage to support the conduct of our clinical trials;
- obtaining IRB approval at each clinical trial site;
- recruiting a sufficient number of suitable patients to participate in a trial;
- patients failing to comply with trial protocol or dropping out of a trial, rendering them not evaluable for study endpoints;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the availability of any applicable combination therapies;
- developments in the safety and efficacy of any applicable combination therapies;
- the need to add new clinical trial sites; or
- delays in the testing, validation and manufacturing of product candidates and the delivery of these product candidates to clinical trial sites.
- We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:
- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- regulators or IRBs may not authorize us, our collaborators, or our investigators to commence a clinical trial or to conduct a clinical trial at a prospective site;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated, or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;



- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects, safety or efficacy concerns, or any particular combination therapy or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- for clinical trials testing combination treatment of our product candidates with third-party drug products, delays in procuring such third-party drug products and the delivery of such third-party drug products to clinical trial sites, or the inability to procure such third-party drug products at all; and
- regulators revising the requirements for approving our product candidates, including as a result of newly approved agents changing the standard of care of an indication.

Any unforeseen events may cause us to be required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, or to be unable to successfully complete clinical trials of our product candidates or other testing. Clinical trial or test results may also not be positive or may be only modestly positive or may have safety concerns. For example, in the APX005M-002 Trial, we enrolled 95 patients with non-small cell lung cancer ("NSCLC") who were either immunotherapy naïve or who had progressed while on anti-PD(L)1 therapy and treated those patients with sotigalimab in combination with nivolumab. Although we observed a modest number of objective responses in immunotherapy naïve patients and stable disease in patients who had previously progressed on or were refractory to prior anti-PD-(L)1 therapy, the data did not support advancing the development of sotigalimab in these lines of therapy in patients with NSCLC. Any of the foregoing events may cause us to incur unplanned costs, be delayed in obtaining marketing approval, if ever, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements, or have the drug removed from the market after obtaining marketing approval.

## The outcome of preclinical testing and early clinical trials that we obtain and that we publish may not predict the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or comparable foreign regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. In particular, no compound with the mechanism of action of sotigalimab has been commercialized, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety results sufficient to obtain marketing approval to market our product candidates.

## Summary or preliminary data from our clinical trials that we announce or publish may change as new or revised patient data becomes available, and is subject to source verification procedures that could result in material changes in the final data.

As more patient data becomes available, we may publicly disclose new or revised preliminary data from our clinical trials. These preliminary updates are based on analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the summary or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Summary or preliminary data also remain subject to source verification procedures that may result in the final data being materially different from the summary or preliminary data we previously published. As a result, summary or preliminary 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. Preliminary data from clinical trials that we conduct may not be indicative of the final results of the trials and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between preliminary data and final data could significantly harm our business and prospects. Further, additional disclosure of preliminary data by us or by our competitors in the future could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Interested parties 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 preliminary or topline 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, our product candidates may be harmed, which could harm our business, financial condition, results of operations, and prospects.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols, use in combination with other therapies, and the rate of discontinuations by clinical trial participants. In addition, we may use patient-reported outcome assessments in some of our clinical trials, which involve patients' subjective assessments of efficacy of the treatments they receive in the trial. Such assessments can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

## Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community. For example, current standard-of-care cancer treatments, such as existing chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. The degree of market acceptance of any of our approved product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the approval of other new therapies for the same indications;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our products, if approved, such as boxed warnings, contraindications in labeling, or restrictions on use of our products together with other medications, or a risk evaluation and mitigation strategy ("REMS"), if any, which may not be required of alternative treatments and competitor products;

- the potential and perceived advantages of product candidates over alternative treatments or in combination therapies;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the effectiveness of sales and marketing efforts;
- the willingness of the target population to try new therapies and of physicians to prescribe these therapies; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, and patients, we may generate less revenue from that product candidate than anticipated, which could harm our financial results.

## The sizes of the patient populations suffering from some of the diseases we are targeting may be based on estimates that are inaccurate, may be small, or may be smaller than estimated.

We rely on estimates to project the incidence and prevalence of diseases we are targeting and the subset of patients with these diseases who have the potential to benefit from treatment with sotigalimab and our other product candidates. We derive these estimates from a variety of sources, including United States and global cancer databases, scientific literature, surveys of clinics, physician interviews, patient foundations, and market research, and they may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for sotigalimab and any other future product candidates may be more limited than we originally estimated or may not be amenable to treatment with sotigalimab and any other product candidates, if and when approved. For example, in March 2022, the FDA approved nivolumab and relatlimab-rmbw (Opdualag<sup>TM</sup>) for use in patients with unresectable or metastatic melanoma, which may limit the number of patients with unresectable or metastatic melanoma that have progressive disease during treatment with anti-PD-(L)1 therapy, which would be the target population for a potential registration-enabling study of sotigalimab in combination with a PD-(L)1 inhibitor that we are considering. Even if we obtain significant market share for sotigalimab and any other product candidates, small potential target populations for certain indications means we may never achieve profitability without obtaining market approval for additional indications.

## Many of our additional internal programs, including APX601, are at earlier stages of development than sotigalimab and may fail in development or suffer delays, including if we are unable to raise adequate additional funding, that adversely affect their commercial viability.

Other than sotigalimab, all of our internal programs are in preclinical development or at the research stage and may fail in development or suffer delays that adversely affect their commercial viability. These programs may fail to yield product candidates. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care, and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later-stage clinical trials of the product candidate. The success of any product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- the successful enrollment of patients in, and the completion of, clinical trials;

- the timely manufacture of sufficient quantities of the product candidate, and any combination therapy, for use in clinical trials; and
- acceptable adverse profile in the clinical trials.

We will need additional funding to continue to advance the development of our other internal programs, including APX601. If we are unable to secure adequate funding to continue such development, we expect that we will be required to delay or stop the development of such programs.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this *"Risk Factors"* section. Accordingly, we cannot assure you that we will ever develop, obtain regulatory approval of, commercialize, or generate significant revenue from any product candidate.

#### Any product candidates we develop may become subject to unfavorable third-party reimbursement practices and pricing regulations.

The availability and extent of coverage and adequate reimbursement by governmental and private payors is essential for most patients to afford the expense of antibody therapeutics like sotigalimab and our other product candidates. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers, and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. In the United States, principal decisions about reimbursement for new products are typically made by Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. As a result, the coverage determination process is often time-consuming and costly. This process 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.

Increasingly, third-party payors require that drug companies provide them with predetermined discounts from list prices and challenge the prices charged for medical products. Further, such payors increasingly challenge the price, examine the medical necessity and review the cost effectiveness of medical drug products. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear.

Third-party payors may limit coverage to specific drug products on an approved list, known as a formulary, which might not include all FDAapproved drugs for a particular indication. We may need to conduct expensive studies to demonstrate the medical necessity and cost-effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

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, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for 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 product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates. Coverage policies and third-party reimbursement rates may change at any time. Even if we attain favorable coverage and reimbursement status for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

## If our competitors develop and market products that are more effective, safer, or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The biotechnology industry is highly competitive and subject to rapid and significant technological change. Moreover, the oncology field is characterized by strong and increasing competition, with a strong emphasis on intellectual property. Products we may develop in the future for the treatment of cancer and any other diseases are likely to face competition from other drugs and therapies, including those of which we may not currently be aware. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

Major multinational pharmaceutical and biotechnology companies, emerging and start-up companies, universities, and other research institutions, could focus their future efforts on developing competing therapies and treatments for any of the indications we are currently targeting or may target in the future. For example, each of Alligator Bioscience AB, Celldex Therapeutics, Inc., Seagen Inc., Lyvgen Biopharma, Eucure Biopharma, a subsidiary of Biocytogen, Hoffmann-La Roche AG, and AbbVie Inc. are developing CD40-based antibody product candidates for solid tumor oncology indications that are in clinical trials, typically in combination therapies, and other companies and institutions have other CD40-based product candidates in development.

Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients, and manufacturing biotechnology products. These companies also have significantly greater research, development, and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of any of these factors, our competitors may succeed in obtaining approval from the FDA, EMA, or foreign regulatory authorities or discovering, developing, and commercializing products in our field before or more successfully than we do.

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

## We have limited resources and are currently focusing our efforts on developing sotigalimab. As a result, we may fail to capitalize on other product candidates or indications that may ultimately have proven to be more profitable.

We are currently focusing our efforts on completing clinical trials of sotigalimab for a variety of indications, including sarcoma, esophageal and GEJ cancers and melanoma. As a result, we may forego or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable product candidates or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other strategic 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 are developing some of our product candidates for use in combination with standard-of-care as well as emerging or experimental cancer therapies, which exposes us to several risks beyond our control.

We are developing some of our product candidates, including sotigalimab, for use in combination with current standard of care or other emerging or experimental cancer therapies. This exposes us to supply risk to the extent there is not an adequate supply of these therapies for use in combination with our product candidates, either in clinical trials or after any approval, as well as pricing risk if these combination therapies are expensive and the addition of our product candidates would be too costly to support reimbursement or payor coverage. In particular, providers of some of these emerging or experimental therapies have been contributing their therapies to use in combination trials at generally no or limited cost to us. If this were to change, our trial costs could increase substantially. Also, although combinations with an experimental agent that has not been approved may prove to be clinically beneficial, the experimental agent will still need to meet regulatory approval requirements for the combined therapy to become commercially available. In addition, if the standard of care were to evolve or change, the clinical utility of our product candidates could be diminished or eliminated. If any of these were to occur, our business could be materially harmed.

## We may use companion diagnostics in the future in our development programs, and if such companion diagnostics for our product candidates are not successfully, and in a timely manner, validated, developed, or approved, we may not achieve marketing approval or realize the full commercial potential of our product candidates.

We may use companion diagnostics in our future product candidate development programs. If such companion diagnostics are developed in conjunction with clinical programs, the FDA, EMA, or comparable regulatory authority may require regulatory approval of a companion diagnostic as a condition to approval of the product candidate. For example, if we use a diagnostic to test which patients are most likely to benefit from our product candidate for the treatment of a particular indication as a criterion for enrollment, then we will likely be required to obtain FDA approval or clearance of the companion diagnostic, concurrent with approval of our product candidate. We may also be required to demonstrate to the FDA the predictive utility of a companion diagnostic, i.e., that the diagnostic selects for patients in whom the therapy will be effective or more effective compared to patients not selected for by the diagnostic. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We do not currently have any agreement in place with any third party to develop or commercialize companion diagnostics for any of our product candidates. Companion diagnostics are subject to regulation by the FDA, the EMA, and other foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization.

If we or our partners, or any third party, are unable to successfully develop companion diagnostics in the future in our product candidates, or experience delays in doing so:

- the development of our product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our planned clinical trials;
- our product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients targeted by our product candidates.

Changes in how the FDA regulations companion diagnostics, including laboratory-developed tests, can impact our clinical development plans for our product candidates. For example, in June 2023, the FDA announced a new voluntary pilot program through which drug manufactures can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval. Based on assessment of the performance information, the FDA will publish the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug to help laboratories identify specific biomarkers for their development of laboratory-developed tests, and to ensure more consistent performance of these tests for drug selection and improved cancer patient care. We will continue to evaluate the impact of the FDA guidance documents and other developments in the diagnostic space on our development plans and strategy. In addition, any future product candidates developed in conjunction with companion diagnostics may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic, the requirement of samples for testing, or the need to complete additional procedures to identify genetic markers prior to administering our product candidates. If any of these events were to occur, it would significantly harm our business, results of operations and prospects.

## Our business entails a significant risk of product liability, and if we do not obtain sufficient insurance coverage, the costs of product liability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing, and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA, or other regulatory investigation of the safety and effectiveness of our products, our manufacturing processes and facilities, or our marketing programs. Such regulatory investigation could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, and substantial monetary awards to trial participants or patients. We would expect to obtain product liability insurance prior to marketing any of our product candidates. Any insurance Apexigen has now or that we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

### Risks Related to Regulatory Approval and Other Legal Compliance Matters for Our Product Candidates

## The regulatory approval processes of the FDA, EMA, and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA, and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity, and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. For example, FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. We have not submitted for, or obtained regulatory approval for, any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including the following:

- the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design, implementation, or results of our clinical trials;
- the FDA, EMA, or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only
  moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing
  approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety and efficacy in the full
  population for which we seek approval, including for example due to biologic and genetic differences that might occur in subjects in certain
  populations such as defined by race or other factors;



- we may be unable to demonstrate to the FDA, EMA, or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio when compared to the standard of care is acceptable;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application ("BLA"), New Drug Application ("NDA"), or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA, or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for a proposed indication is acceptable;
- the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2018 and 2019, or other FDA priorities, such as responding to COVID-19, may result in significant reductions to, or demands on, the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

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

## Our product candidates may cause undesirable side effects or have other properties that could prevent their regulatory approval or result in significant negative consequences.

Adverse events or other 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 regulatory approval by the FDA, EMA, or other comparable foreign regulatory authorities. Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the trial, and/or result in potential product liability claims. Regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale.

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

- regulatory authorities may withdraw approvals of such product and cause us to recall our products;
- regulatory authorities may require additional warnings on the label or impose a more restrictive, narrower indication for use of the agent;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements, such as boxed warning on the packaging, to assure safe use;



- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

## For any current and future clinical trials for our product candidates outside the United States, the FDA, EMA, and applicable foreign regulatory authorities may not accept data from such trials.

We conduct clinical trials outside the United States, including in Europe, and we may choose to conduct future clinical trials outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA, or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the United States population and United States medical practice, and the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice ("GCP") regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have comparable approval requirements, including appropriate examination of the product in the country-specific population. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA, or any applicable foreign regulatory authority does not accept such data, it may result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA, EMA, or comparable foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fails to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced, and our ability to realize the full market potential of our product candidates will be harmed.

# Even if we apply for and obtain accelerated approval or Breakthrough Therapy, Fast Track or other designation intended to expedite, facilitate or reduce the cost of pursuing development or regulatory review or approval with the FDA or other regulatory authorities for any of our product candidates, there is no guarantee that such designation would lead to faster development, regulatory review, or approval, nor would it increase the likelihood that any such product candidate will receive marketing approval.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for such condition or a substantial improvement over available therapy for such condition, a product candidate sponsor may apply for FDA Fast Track or Breakthrough Therapy designation, and there may be other priority designations available under various regulatory bodies. In the future, we may apply for such priority designation depending on the results of our clinical trials. Even though we may apply for and receive a Fast Track, Breakthrough Therapy or other priority designations, such priority designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with the priority designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track or Breakthrough Therapy designation alone does not guarantee qualification for the FDA's priority review procedures. Further, even if



any of our products obtain Fast Track or Breakthrough Therapy designation, this may not lead to earlier regulatory approval or commercialization of our products due to the extensive and time-consuming steps necessary to obtain FDA approval and commercialize a product candidate. In December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

#### Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

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

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA, and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to Good Manufacturing Practice ("GMP") regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any BLA, NDA, or Marketing Authorization Application ("MAA"). Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including potentially the requirement to implement a REMS), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA, and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing, or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;

- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, this would significantly harm our business, financial condition, results of operations, and growth prospects.

#### Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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

- the demand for our products after obtaining any regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as 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, lower reimbursement and new payment methodologies. For example, in August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The prescription drug provisions of the Inflation Reduction Act and other healthcare reforms that may be implemented in the future could lower the price that we receive for any approved product. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, including uncertainties created by the prescription drug price negotiation provisions of the Inflation Reduction Act, as well as future legislative, executive, and administrative actions and agency rules implemented by the government, on us and the pharmaceutical industry as a whole is unclear. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to:

- comply with the laws of the FDA, EMA and other comparable foreign regulatory authorities;
- provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or
- report financial information or data accurately or to disclose unauthorized activities to us.

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We plan to adopt a code of business conduct and ethics in connection with this offering, but it is not always possible to identify and deter misconduct by employees and 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. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

## If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations, and financial conditions could be adversely affected.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be subject to various federal and state fraud and abuse laws. The laws that may impact our operations include the following:

- The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. 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 False Claims Act.
- Federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, impose criminal and civil penalties, including through civil actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any



materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization.
- The federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the HHS under the Open Payments Program, information related to payments or other transfers of value made to covered recipients, as defined by law, including physicians, certain non-physician providers, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws may apply to pharmaceutical business practices, including research, distribution, sales, and marketing arrangements, as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers.

- State laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources.
- State laws also require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration, and items of value provided to healthcare professionals and entities.
- State and foreign laws and regulations also govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Further, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove costly.



## If we or any clinical collaborators, CROs, contract manufacturers, or other contractors and suppliers that we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and any clinical collaborators, CROs, contract manufacturers, or other contractors and suppliers that we engage are subject to numerous federal, state, and local environmental, health and safety laws, regulations, and permitting requirements, including:

- those governing laboratory procedures;
- the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes;
- the emission and discharge of hazardous materials into the ground, air and water; and
- employee health and safety.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

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

#### Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the researchers with whom we conduct clinical trials, and the healthcare providers who prescribe pharmaceuticals, are employed by their government, and the purchasers of pharmaceuticals are government entities. As a result, our dealings with these researchers, prescribers, and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our bu

## Failure to comply with privacy and data protection laws, regulations, or contractual obligations could lead to government enforcement actions (which could include civil or criminal penalties), private disputes and litigation, and/or adverse publicity and could negatively affect our operating results and business.

We receive, generate, and store significant and increasing volumes of sensitive and personal information, such as employee, personal, patient and collaborator data. In addition, we actively seek access to medical information, including patient data, through research and development partnerships and collaborations or otherwise. We have legal and contractual obligations regarding the protection of confidentiality and appropriate use of personal information. We and our partners may be subject to federal, state, and foreign privacy and data protection laws and regulations (i.e., laws and regulations that address privacy and data security). These privacy and data protection laws and regulations continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, protection, and other processing of health-related and other personal information could apply to our operations or the operations of our partners, including during our clinical trials. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, which establish privacy and security standards that limit the use and disclosure of individually identifiable health information and require the implementation of administrative, physical, and technological safeguards to protect the privacy of individually identifiable health information and ensure the confidentiality, integrity, and availability of electronic protected health information. Determining whether individually identifiable health information has been handled in compliance with applicable privacy laws, regulations, and standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Depending on the facts and circumstances, we could be subject to civil and criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. We cannot be sure how these regulations will be interpreted, enforced, or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Failure to comply with any of these laws or regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation, and loss of goodwill (both in relation to existing and prospective customers), any of which could have a material adverse effect on our business, financial condition, results of operations, or prospects.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or other malicious third parties or viruses or breached due to employee error, malfeasance, or other malicious or inadvertent disruptions. Any such attack, breach, or other security breach or incident, or any interruption, could compromise our networks and the information processed there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, stolen or otherwise processed without authorization. Any such access, loss, other unauthorized processing, or any other security breach or incident, could result in legal claims or proceedings, and liability under federal or state laws and regulations that protect personal information, such as HIPAA and HITECH, and regulatory penalties. Notice of certain security breaches must be made to affected individuals, the Secretary of the HHS, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. The HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. Although we have implemented security measures designed to prevent unauthorized access to patient and other data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from security breaches or incidents, loss, or other unauthorized processing. Unauthorized access, loss, dissemination or other processing could also conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide info

We may collect, use, transfer, or otherwise process personal information from individuals located in the European Economic Area ("EEA"), Switzerland, and the United Kingdom (collectively, "Europe") in connection with our business, including in connection with conducting clinical trials in Europe. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in Europe. The collection, use, and other processing of personal information, including health information, in Europe are governed by laws, regulations, and directives, including the General Data Protection Regulation (EU) 2016/679 ("GDPR"). This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. This legislation imposes significant responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance. In particular, with respect to cross-border transfers of personal data, judicial and regulatory developments in Europe have created uncertainty. In a decision issued by the Court of Justice of the European Union ("CJEU") on July 16, 2020, the CJEU invalidated one mechanism for cross-border personal data transfer, the EU-U.S. Privacy Shield, and imposed additional obligations on companies, including us, relying on standard contractual clauses issued by the European Commission ("SCCs") for cross-border personal data transfers. The European Commission released new SCCs designed to address the CJEU concerns on June 4, 2021, which are required to be implemented. Additionally, the United Kingdom's Information Commissioner's Office issued new standard contractual clauses (the "UK SCCs") to support personal data transfers out of the United Kingdom on February 2, 2022, which also are required to be implemented. The European Commission adopted an adequacy decision in relation to the EU-U.S. Data Privacy Framework ("EU-U.S. DPF") as a cross-border personal data transfer mechanism on July 10, 2023. We have undertaken certain efforts to conform transfers of personal data from Europe to the United States to our understanding of regulatory obligations and applicable guidance of data protection authorities, but the CJEU's decision, the revised SCCs and UK SCCs, regulatory guidance and opinions, and other developments relating to cross-border data transfer may require us to implement additional contractual and technical safeguards for any personal information transferred out of Europe or other regions which may increase compliance costs, lead to increased regulatory scrutiny or liability, may require additional contractual negotiations, and may adversely impact our business, financial condition and operating results. Any actual or alleged failure to comply with the requirements of the GDPR or other laws, regulations, and directives of jurisdictions and regulators within Europe may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, U.S. states are adopting new laws or amending existing laws and regulations, requiring attention to frequently changing regulatory requirements applicable to data related to individuals. For example, California has enacted the California Consumer Privacy Act ("CCPA"). The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and which can include any of our current or future employees who may be California residents or any other California residents whose data we collect or process) and provide such residents new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and trials (both preclinical or clinical), the CCPA may increase our compliance costs and potential liability. Additionally, the California residents related to consumer data and expanding consumers' right with respect to certain sensitive personal information. The CCPA became operative on January 1, 2022, with enforcement to commence on March 29, 2024, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Additionally, other U.S. states and the U.S. federal government continue to propose, and in the case of certain states adopt, privacy-focused legislation, such as laws enacted in Colorado, Virginia, Utah, Connecticut, Florida, Montana, Oregon, Texas, Tennessee, Iowa, and Indiana. Aspects of these state laws remain unclear, resulting in further uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to c

Failure to comply with U.S. and international privacy and data protection laws or regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with privacy and data protection laws or regulations or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third parties fail to adequately safeguard confidential personal, employee, patient, or other information or data, or if such information or data are wrongfully used by us or third parties or disclosed to unauthorized persons or entities, our reputation could suffer and we could be subject to claims for damages or other liabilities, regulatory investigations and enforcement action, litigation, the imposition of fines or other penalties, and significant costs for remediation. Any of these risks could have a material adverse effect on our business, financial condition, results of operations, or prospects.

### Risks Related to Employee Matters, Managing Operations and Other Risks Related to Our Business

## Our success is highly dependent on the services of our Chief Executive Officer, Dr. Xiaodong Yang, and our other senior management, and our ability to retain, manage, and motivate highly skilled executive officers and employees.

To succeed, we must retain, manage, and motivate qualified clinical, scientific, technical, and management personnel, and we face significant competition for experienced personnel, especially in the biotechnology industry in the San Francisco Bay Area of California. We are highly dependent on the principal members of our management and scientific and medical staff, particularly our Chief Executive Officer, Dr. Xiaodong Yang. If we do not succeed in retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers, including Dr. Yang, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We have recently been, and could in the future be, required to expend significant financial resources on employee retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer, in particular given the current focus on pursuing a strategic transaction. If we are unable to continue to motivate and retain high-quality personnel, our ability to evaluate and pursue strategic alternatives will be harmed, and the potential for resuming research and development activities and successfully implementing our business strategy may be limited.

### In order to successfully implement our plans and strategies, we will be substantially dependent on a reduced workforce, which added responsibilities could strain our employees and members of management and increase our reliance on third-parties to provide certain services.

As of July 31, 2023, Apexigen had 11 full-time employees. In order to successfully pursue a strategic transaction, fulfill our obligations as a public reporting company and maintain our development and commercialization plans and strategies, we will be substantially dependent upon the efforts of these 11 employees. We may experience difficulties in implementing such objectives given the significant added responsibilities on our remaining employees and members of management.

Further, we rely on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical management and manufacturing. We have significantly reduced our research and development activities since February 2023 in order to explore the potential for a strategic transaction; however to the extent we maintain such activities we may be required to rely more heavily on such outside contractors. We cannot assure you that the services of these outside contractors will continue to be available to us on a timely basis when needed. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not obtain marketing approval of our current and any future product candidates or otherwise advance our business. We cannot assure you that we will manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are unable to effectively manage our organization with a reduced workforce and maintain our relationships with contractors and consultants to support our clinical management and manufacturing activities, our ability to successfully implement our business plans and strategies will be harmed.

#### If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates after any approvals, we may not successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team for the marketing, sales and distribution of any of our product candidates that may obtain regulatory approval in the future. In order to commercialize any product candidates, we will need to build marketing, sales, distribution, managerial, and other non-technical capabilities or make arrangements with third parties to

perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, 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 will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

## Our anticipated international operations may expose us to business, tax, regulatory, political, operational, financial, pricing, and reimbursement risks associated with doing business outside of the United States.

Our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our current and any future product candidates in patient populations outside the United States. If our product candidates are approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting, and changing laws and regulations such as privacy and data protection laws and regulations, tax laws, export and import
  restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- taxation of future foreign earnings may increase our effective tax rate, which could adversely affect our cash flows, and overall financial condition;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the FCPA, its accounting provisions or its anti-bribery provisions, or provisions of anti-corruption or anti-bribery laws in other countries.



Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

#### **Risks Related to Intellectual Property**

## If we do not obtain, maintain or protect our intellectual property rights in products we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, third parties could develop and commercialize products and technology similar or identical to ours, and we may not compete effectively in our market.

Our success depends in significant part on our and our current or future licensors' ability to obtain, maintain and protect patents and other intellectual property rights and operate without infringing, misappropriating, or otherwise violating the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have developed that are important to our business, including related to our product candidates. We have also licensed from third parties' rights to patents and other intellectual property, including from Epitomics, Inc., an Abcam Company ("Epitomics"), with respect to rabbit monoclonal antibodies generated using Epitomics' technology in the field of pharmaceutical products for human or veterinary use. If we or our licensors are unable to obtain or maintain patent protection with respect to such inventions and technology, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we and our current or future licensors may not prepare, file, prosecute, maintain, and enforce all necessary or desirable patent applications at a reasonable cost or in a timely manner. Patents may be invalidated and patent applications may not be granted for a number of reasons, including known and unknown prior art, deficiencies in the patent applications or the lack of novelty of the underlying inventions or technology. It is also possible that we or our current and future licensors will fail to identify patentable aspects of inventions made in the course of research, development and commercialization activities 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, development, and commercialization activities, such as our employees, collaborators, CROs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such activities before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our current or future licensors were the first to make the inventions claimed in our owned or any licensed patents or patent applications, or that we or our current or future licensors were the first to file for patent protection of such inventions.

Moreover, in some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering products or technology that we license from third parties and are reliant on our current and future licensors. For example, pursuant to our license agreement with Epitomics, Inc., Epitomics is responsible for the filing, prosecution and maintenance of the patents and patent applications licensed to us. Therefore, these patents and applications may not be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our current or future licensors fail to prosecute, maintain, enforce or defend such patents and other intellectual property rights, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our current or future licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Moreover, the patent examination process may require us or our current and future licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Additionally, the scope of patent protection can be reinterpreted after issuance. Even if our or our current or future licensors' pending and future 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 that we hold or in-license may be challenged, narrowed, circumvented, or invalidated by third parties in court or in patent offices in the United States and abroad. Our and our current or future licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Our competitors or other third parties may also circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

We cannot assure you that we have found all of the potentially relevant prior art relating to our patents and patent applications. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. For example, there are a number of third-party patents and patent applications relating to the engineering of antibodies, including with respect to the CD40 binding and fragment crystallizable ("Fc") domains, that may have earlier priority or publication dates and may be asserted as prior art against our patents and patent applications. Even if our patents do issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, inter partes reviews, nullification or derivation actions in court or before patent offices, or similar proceedings challenging the inventorship, validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, the patent rights we own or license, allow third parties to commercialize our technology or products and compete directly with us, without payment to us.

Moreover, we, or our current or future licensors, may have to participate in interference proceedings declared by the United States Patent and Trademark Office ("USPTO") to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates, including sotigalimab. 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. Consequently, we do not know whether any of our technology or product candidates will be protectable or remain protected by valid and enforceable patents.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our current and future licensors were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

#### We may not protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our current and future licensors' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our current and future licensors may not prevent third parties from practicing our and our current or future licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our current or future licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our current or future licensors' 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 and our current and future licensors 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 and our current or future licensors' 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, which could make it difficult for us and our current and future licensors to stop the infringement of our and our current or future licensors' patents or marketing of competing products in violation of our and our current or future licensors' intellectual property and proprietary rights generally. Proceedings to enforce our and our current or future licensors' intellectual property and proprietary rights and divert our and our current or future licensors' efforts and attention from other aspects of our business, could put our and our current or future licensors' patents at risk of being invalidated or interpreted narrowly, could put our and our current or future licensors. We or our current and future licensors may not prevail in any lawsuits that we or our current and future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Some jurisdictions may refuse to honor intellectual property rights due to legislation or geopolitical reasons, such as Russia recently stating that it will not honor patent rights of companies from countries that have imposed sanctions on Russia in response to the war in Ukraine. Accordingly, our and our current and future licensors' efforts to enforce intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 or our current and future licensors 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.

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

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, timeconsuming, and inherently uncertain. 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. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act ("Leahy-Smith Act"), could increase those uncertainties and costs. The Leahy-Smith Act includes provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and may also 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. In addition, assuming that other requirements for patentability are met, prior to March 15, 2013, in the United States, the first to invent the claimed invention was entitled to the patent while outside the United States, the first to file a patent application was entitled to the patent. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material advers

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. 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 U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on any issued patent or patent application are due to be paid to the USPTO and various government patent agencies outside of the United States in several stages over the lifetime of our owned or licensed patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can, in some cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or our current and future licensors fail to maintain the patents and patent applications covering our product candidates, our patent protection could be reduced or eliminated and our competitors might be better able to enter the market with competing products or technology, which could have a material adverse effect on our business, financial condition, results of operation, and prospects.

## If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.

We are a party to a number of intellectual property and technology licenses that are important to our business. For example, Apexigen obtained an exclusive license from Epitomics under certain intellectual property related to rabbit monoclonal antibodies generated using Epitomics' technology in the field of pharmaceutical products for human or veterinary use that has certain ongoing payment and other obligations even though the license agreement has now expired. In addition, if we fail to comply with our obligations under these technology agreements, including payment and diligence terms, or other specified events occur such as our insolvency, our current and future licensors may have the right to terminate these agreements, in which event we may not develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could adversely affect the value of the technology or product candidate being developed or licensed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our existing collaborative development relationships and any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current and future licensors and us; and
- the priority of invention of patented technology.

In addition, the agreements under which Apexigen licenses intellectual property or technology from third parties are generally complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, result of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

#### We may not succeed in obtaining necessary rights to any product candidates we may develop through acquisitions and in-licenses.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our current or future product candidates. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. Moreover, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we may develop. In addition, with respect to any patents we co-own with third parties, we may require licenses to such co-owners' interest to such patents. 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 product candidates we 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 or commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. As a result, we may be unable to obtain any such licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. In addition, even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may license their rights to other third parties, including our competitors, and such third parties could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

## Third parties may initiate legal proceedings against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our and our current or future licensors' proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us or our current and future licensors alleging that we or our current and future licensors infringe, misappropriate, or otherwise violate their intellectual property rights. In addition, we or our current and future licensors may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews, or derivation proceedings in the United States or other jurisdictions. These proceedings can be expensive and time-consuming, and many of our or our current and future licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our current and future licensors.



There are third-party patents and, if issued as patents, patent applications relating to the engineering of antibodies, including with respect to CD40 and Fc domains, that may be construed to cover our product candidates, including sotigalimab. The third parties that control these patents may allege that our product candidates, including sotigalimab, infringe these patents. Parties making infringement, misappropriation, or other intellectual property claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In addition, even if we believe any third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of validity, enforceability, priority, or non-infringement. A court of competent jurisdiction could hold that such third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any of our products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such third-party U.S. patents in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. An unfavorable outcome could require us or our current and future licensors to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our current and future licensors a license on commercially reasonable terms or at all. Even if we or our current and future licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our current and future licensors, and it could require us to make substantial licensing and royalty payments. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement, misappropriation, or other violation of thirdparty intellectual property could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

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

Many of our employees, consultants, and advisors, including our senior management, were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure, and/or non-competition agreements in connection with such previous employment. 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 confidential information or 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 prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract 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.

#### Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Trade secrets can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality 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 obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us. Failure on our part to adequately protect our trade secrets and our confidential information wou

#### Issued patents covering one or more of our product candidates or technologies could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable, and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners' efforts, we or our licensors or collaboration partners may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the European Union and the United States. We may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our technologies, including our APXiMAB platform, and then compete directly with us, without payment to us.

If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, or non-enablement. A claim for unenforceability could involve an allegation that someone connected with prosecution of the patent withheld relevant information from the European Patent Office or the USPTO or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, 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 technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability during patent litigation 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 defendant 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 one or more of our product candidates or certain aspects of our APXiMAB platform technologies. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm our business and financial results. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

#### We may become involved in disputes or lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, timeconsuming, unsuccessful, and lead to challenges to our intellectual property ownership.

Competitors and other third parties may infringe, misappropriate, or otherwise violate our issued patents or other intellectual property of our licensors, or we or our licensors may be required to defend against claims of infringement, misappropriation, or other violation. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Other disputes may arise related to intellectual property rights that we believe are derived from, or related to, our patents or technology, including with respect to sotigalimab. For example, we are aware of certain patent applications filed by a former collaborator covering biomarkers and patient selection discoveries related to our sotiga program. We believe that we own the intellectual property to us, but there is no guarantee that we will come to a satisfactory resolution of this matter.

To counter infringement, misappropriation, or other unauthorized use, we or our licensors may be required to negotiate a solution to such dispute or file infringement claims, either of which can be expensive and time-consuming. Any claims we or our licensors assert against perceived infringers could provoke these parties to assert counterclaims against us or our licensors alleging that we or our licensors infringe their patents or that our or our licensors' patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours or one of our licensors' is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly.

We may find it impractical or undesirable to enforce our intellectual property against some third parties. 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.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our or our licensors' patents or patent applications. If we or our licensors are unsuccessful in any interference proceedings to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority of inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or narrowing of our owned or licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

Any of the foregoing intellectual property disputes or litigation could result in a material adverse effect on our business, financial condition, results of operations, or prospects.

#### Intellectual property litigation or proceedings could cause us to spend substantial resources and distract our personnel.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. 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. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not prevent third parties from infringing upon, misappropriating, or otherwise violating our intellectual property. Any of the foregoing events could harm our business, financial condition, results of operations, and prospects.

#### If we do not obtain patent term extension or data exclusivity for any product candidates we may develop, our business may be materially harmed.

Patents have a limited lifespan. Due to the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. 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. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. For example, certain of our owned patents that cover sotigalimab will begin to expire in 2032, absent extensions, in the United States and similar patent applications are pending in foreign jurisdictions. At the time of the expiration of the relevant patents, the underlying technology covered by such patents can be used by any third party, including competitors. Although the patent term extensions under the Drug Price Competition and Patent Term Restoration Action of 1984 ("Hatch-Waxman Act") in the United States may be available to extend the patent term, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension 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. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

### If our trademark and tradenames are not adequately protected, then we may not build name recognition in our markets and our business may be adversely affected.

We cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. We cannot assure you that any future trademark applications that we will file will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. An opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings, which may force us to rebrand our name.

#### 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 make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

#### **Risks Related to Our Dependence on Third Parties**

### We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We do not have the ability to independently conduct our clinical trials. We currently rely on third parties to conduct clinical trials of its product candidates, including ISTs sponsored by third parties; these third parties also include CROs, clinical data management organizations, medical institutions and clinical investigators. We expect to continue to rely upon third parties to conduct additional clinical trials of our product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. In some cases, these third parties may not provide us with information about the ongoing clinical trials on a timely basis. The third parties may also violate the terms of the agreements governing such clinical trials in various ways, including asserting intellectual property rights that contractually belong to us. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it will delay our drug development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current GMP regulations. Our failure or the failure of the third parties we engage to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain time frames. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

#### We contract with third parties for the production of sotigalimab and our other product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization and for additional product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture our product candidates for use in clinical development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates in compliance with GMP requirements for clinical trials under the guidance of members of our organization. We currently rely on a single third-party manufacturer, WuXi Biologics (Hong Kong) Limited ("WuXi"), for the manufacture of our product candidates sotiga and APX601. We expect the quantity and stability of our current supply of sotiga, which was produced by a prior third-party manufacturer, will be sufficient to supply our currently ongoing clinical trials into the fourth quarter of 2023.



WuXi has successfully manufactured sotiga drug substance and labeled drug product for clinical trial use as of March 2023. We continue to work with the FDA to complete a plan to demonstrate comparability of the WuXi-generated drug product with the sotiga drug product we have used in clinical trials historically, which was produced by a prior third-party manufacturer. If FDA or other relevant regulatory authorities do not accept our comparability protocol or we do not adequately demonstrate the comparability of the WuXi-generated drug product with the drug product we have used in past clinical trials, we may not be able to rely on clinical trial data we have generated to date using the drug product from that prior third-party manufacturer.

The manufacture of biologic therapeutics is complex. It is anticipated that during development from early clinical trials to commercialization that changes to the manufacturing cell line, manufacturing process or analytical methods will occur. These changes carry the risk that the intended goals of such changes are not achievable and that further development work may be needed to reach these goals, which may delay our ability to meet clinical or commercial supply needs. Our change in the manufacturing site, cell line, process and analytical methods for sotiga represent a specific elevated risk for the sotiga program. However, we currently have no alternative manufacturer in place for sotiga and APX601 drug substance and drug product. For the APX601 product candidate, we have successfully completed drug substance and drug product runs at WuXi. We have not yet performed labeling and packaging runs for APX601 and will need to do so prior to initiating any clinical development of APX601.

If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply, or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials, such as occurred with the prior switchover by us to a new contract manufacturer. Replacement of our sole manufacturer would likely result in substantial delay and could interrupt our clinical trials if we had not previously obtained enough supply of our product candidates.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture our product candidates according to our specifications;
- the possible failure of the third party to manufacture our product candidate according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible failure of our third-party manufacturer to procure raw materials from third-party suppliers and potential exposure to supply chain issues impacting delivery dates, quality, quantity and pricing of raw materials, including due to the COVID-19 pandemic or other public health emergencies, which may result in additional costs and delays in production of clinical trial materials, commercial product and regulatory approvals;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or, following approval by regulatory authorities, of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have control over many aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners, including WuXi, for compliance with GMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with U.S. export control regulations, GMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA, or others, they will not secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for, or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs and harm our business and results of operations.

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

#### We may not gain the efficiencies we expect from further scale-up of manufacturing of our product candidates, and our third-party manufacturers may be unable to successfully scale up manufacturing in sufficient quality and quantity for our product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates.

We expect that our third-party manufacturer, WuXi, will manufacture our product candidates at a scale and on a timeline that is sufficient for us to complete our planned clinical trials and, if we receive marketing approval, to commercialize our product candidates, including sotigalimab, for the indications we are currently targeting. However, we may consider increasing the batch scale to gain cost efficiencies. If our current manufacturer or any other manufacturer we use is unable to scale-up the manufacture of our product candidates at such time, we may not gain such cost efficiencies and may not realize the benefits that would typically be expected from further scale-up of manufacturing. In addition, quality or other technical issues may arise during scale-up activities. If our third-party manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

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

As product candidates progress through preclinical and late-stage 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 yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. The FDA may not approve our third-party manufacturers' processes or facilities. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, and jeopardize our ability to commercialize our product candidates and generate revenue.

# We have and may in the future enter into additional agreements with third parties under which those parties have or will be granted a license to develop product candidates discovered using our APXiMAB platform. If any such programs are not successful or if disputes arise related to such programs, we may not realize the full commercial benefits from such programs.

Our APXiMAB platform has enabled the discovery of several product candidates with potential utility in multiple therapeutic areas and has resulted in five programs that have been licensed to third parties, including larger global biopharmaceutical companies and mid-sized regional or China-focused companies. Our likely counterparties for future licensing and collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. Such arrangements generally allow the licensing parties to control the amount and timing of resources that they dedicate to the development or potential commercialization of any product candidates they develop from the technology we have licensed to them, subject to any territorial or field of use restrictions in the license. In addition, we partnered with ESBATech AG, which was acquired by Alcon and later Novartis to provide rabbit monoclonal antibodies in order to develop product candidates for certain diseases.

We typically negotiate milestone payments and royalty fees from our licensees that will require various levels of success with their product candidate development program in order for us to generate revenue from them. Our ability to generate revenue from these licensing arrangements will depend on our counterparties' abilities to successfully develop and commercialize the product candidates they are developing. We cannot predict the success of any licensing program that we enter into or whether such program will lead to any meaningful milestone or royalty revenue to us.

Licensing programs involving third-party development of product candidates derived from our licensed technology pose the following risks to us:

- counterparties generally have significant discretion, if not total control, in determining the efforts and resources that they will apply to these development efforts;
- counterparties may not properly or adequately obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our intellectual property or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual propertyrelated proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;
- counterparties may own or co-own with us intellectual property covering their product candidates, and, in such cases, we typically will not have the exclusive right to commercialize such intellectual property or their product candidates based on the terms of the licensing agreement;
- we may need the cooperation of these counterparties to enforce or defend any intellectual property we contribute to the program;
- counterparties typically will control the interactions with regulatory authorities related to their product candidates, which may impact our ability to obtain and maintain regulatory approval of our own product candidates;
- disputes may arise between the counterparties and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;
- counterparties may decide to not pursue development and commercialization of any product candidates that are derived from our licensed technology, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the counterparties' strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities, or counterparties may elect to fund or commercialize a competing product;
- counterparties could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- counterparties may not commit sufficient resources to the marketing and distribution of their product candidates, resulting in lower royalties to us;
- counterparties may grant sublicenses to our technology or undergo a change of control, and the sublicensees or new owners may decide to pursue a strategy with respect to the program which is not in our best interest;
- counterparties may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to
  valuable technology, know-how, or intellectual property of the counterparty relating to our technology in relation to the terms of the licensing
  agreement;
- if these counterparties do not satisfy their obligations under our agreements with them, or if they terminate our licensing agreements with them, we may be adversely impacted; and
- licensing agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

Beovu® is a drug product developed by Novartis covered under the ESBATech Agreement with us. Novartis obtained approval for Beovu for use in neovascular (wet) age-related macular degeneration ("AMD") and as a treatment of visual impairment due to diabetic macular edema, Novartis continues to develop Beovu for other indications. Under the terms of the ESBATech agreement, Novartis is obligated to pay us a very low single-digit royalty on worldwide net sales of Beovu. However, Novartis has disputed its obligation to pay royalties to us under the agreement and continues to pay such royalties under protest. As a result, we have determined that any sales-based royalties received from Novartis for Beovu are currently fully constrained, and we have recorded the royalty proceeds as deferred revenue on our consolidated balance sheet, with the amounts totaling \$6.7 million and \$5.7 million as of June 30, 2023 and December 31, 2022, respectively. If the dispute with Novartis regarding their royalty obligations is not settled favorably through negotiation or if the parties escalate the dispute through arbitration or litigation, there is no guarantee that we will recognize such historic and future royalty revenue in part or at all, we may be required to return the cash received to date for the constrained royalty payments, we may not receive future payments, and we may incur substantial costs and distraction of management related to such dispute. While this dispute continues, the Beovu royalty rights will be impaired which will limit our ability to exercise ownership over or monetize this royalty stream, all of which could have an adverse effect on our business, financial condition, and results of operations.

Many of the risks relating to product development, intellectual property, regulatory approval, and commercialization described in this *"Risk Factors"* section also apply to the activities of our licensees and any negative impact on these counterparties and their product development programs may adversely affect us.

#### If we seek to establish additional collaborations, but are unable to do so, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We are currently seeking to engage a global collaboration partner to advance the development of sotigalimab and may seek to selectively form other collaborations to expand our capabilities, potentially accelerate research and development activities, and provide for commercialization activities by third parties.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

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



If and when we seek to enter into collaborations, we may not negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

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

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

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

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

#### **Other General Risks**

### We face risks related to health epidemics and other outbreaks, such as COVID-19, which could significantly disrupt our operations or otherwise result in material adverse impacts to us.

On May 11, 2023, the federal government ended the COVID-19 public health emergency, which ended a number of temporary changes made to federally funded programs while some continue to be in effect. Consequently, many of the FDA COVID-19 related guidance documents issued during the COVID-19 public health emergency for manufacturers and clinical trial sponsors have expired or were withdrawn with the expiration of the COVID-19 public health emergency declaration, although some COVID-19 related guidance documents continue in effect. The full impact of this termination of the national emergency and the wind-down of the public health emergency on FDA and other regulatory policies and operations are unclear. To the extent we experience any ongoing pandemic disruptions or other public health emergencies, including a resurgence of COVID-19 cases, potential impacts to our business may include:

• delays or difficulties in enrolling and retaining subjects in our ongoing clinical trials and our future clinical trials;

- delays or difficulties in clinical site initiation, including due to difficulties in staffing and recruiting at clinical sites;
- difficulties interpreting data from our clinical trials due to the possible effects of health epidemics or other outbreaks on subjects;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in resources, including our employees, that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people, or due to limitations on travel or other restrictions imposed or recommended by federal or state and local governments;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of some or all of our employees working remotely, including those hired during the COVID-19 pandemic;
- delays in receiving approval from regulatory authorities to initiate our clinical trials;
- interruptions in preclinical studies due to restricted or limited operations at the CROs conducting such studies;
- interruptions or delays in the operations of the FDA or other domestic or foreign regulatory authorities, which may impact review and approval timelines;
- delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical research;
- changes in regulations as part of a response to health epidemics or other outbreaks which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or require us to discontinue the clinical trial altogether;
- interruptions or delays to our development pipeline;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside of the United States.

To the extent another pandemic or other public health epidemic or outbreak adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section and in this *"Risk Factors"* section.

# Our internal computer systems, and those used by our third-party research institution collaborators, other contractors, and consultants, may fail or suffer other breakdowns, cyberattacks or information security breaches and incidents that could compromise the confidentiality, integrity and availability of such systems and data, result in material disruptions of our development programs and business operations, risk disclosure of confidential, financial or proprietary information, and affect our reputation.

Despite the implementation of security measures, our internal computer systems, and those used by our third-party research institution collaborators and other contractors or consultants, may be vulnerable to damage, compromise, disruption and unauthorized access owing to a variety of causes, including system malfunction, natural disasters, terrorism, war and telecommunication and electrical failure, cyberattacks and other forms of hacking by malicious third parties, and inadvertent or intentional actions by our employees, our third-party research institution collaborators, other contractors and consultants, and/or other third parties. As the cyber-threat landscape evolves, attacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. These risks are increased given several of our personnel and those of our collaborators, contractors and consultants work remotely, and threats of cyberattacks by Russia and affiliated actors in response to the war in Ukraine. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other means of effecting denials of service or unavailability of systems or data, and can be deployed through malicious websites, the use of social engineering, and/or other means. If a breakdown, cyberattack, or other information security breach or incident were to occur and cause interruptions in our operations or any loss, corruption, or unavailability of data, it could result in loss or misappropriation of confidential information, including trade secrets, other intellectual property, or financial information, and a material disruption of our development programs and our business operations, any of which could lead to significant delays or setbacks in our research and other further development and commercialization of our product candidates. For example, the loss of clinical trial data from completed, ongoing, or future clinical trials could result in delays in our regulatory approval effort

Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Any disruption or security breach or incident that we or our collaborators and other contractors and consultants suffer, including any such disruption, breach or incident resulting in a loss of, or damage to, data or systems, or inappropriate disclosure, access, loss, or other processing of confidential, financial, proprietary or personal information, including data related to our personnel, could result in loss, disclosure or other unauthorized processing of confidential, financial, proprietary, and personal information, could delay further development and commercialization of our product candidates, and any such event, or the perception any such event has occurred, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. There can be no assurance that we or our collaborators, other contractors and consultants, or other business counterparties will be successful in efforts to detect, prevent, or otherwise respond to security breaches or incidents, or fully recover systems or data from all breakdowns, service interruptions, attacks, or other security breaches or incidents.

Further, notification and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived disruption or security breach or other security incident.

Our insurance coverage may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach or incident of or impacting, our systems or third-party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert attention of management and technical personnel.

#### Our operations are subject to the effects of a rising rate of inflation.

The United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, for example due to increases in the costs of labor and supplies, it will affect our expenses, such as employee compensation and research and development charges. Research and development expenses account for a significant portion of our operating expenses. Such increased charges may not be readily recoverable during the period of time that we are bringing the product candidates to market. Additionally, the United States is experiencing an acute workforce shortage, which in turn, has created a very competitive wage environment that may increase our operating costs. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our consolidated financial condition and results of operations.

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

Our operations, and those of our third-party research institution and pharmaceutical company collaborators, manufacturers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical or public health crises, such as the COVID-19 pandemic, and other natural or man-made disasters or business interruptions, including terrorism and war. In addition, for some of our clinical trials, we rely on third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

The majority of our operations, including our corporate headquarters, are located in the San Francisco Bay Area of California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain customary insurance coverage, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

In February 2022, Russia commenced a war against Ukraine. The sanctions announced by the U.S. and other countries against Russia as a result include restrictions on selling or importing goods, services, or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business, and financial organizations in Russia. The United States and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, threats of cyberattacks, prolonged periods of higher inflation, geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations.

In March 2023, the Federal Deposit Insurance Corporation ("FDIC") took control and was appointed receiver of Silicon Valley Bank ("SVB") due to adverse financial conditions SVB was facing. We held nearly all of our cash and cash equivalents in accounts at SVB at the time the receivership was put in place. As a result of the FDIC's actions, nearly all of our cash and cash equivalents, whether insured or uninsured, were temporarily inaccessible. In May 2023, First Republic Bank was also placed into receivership with the FDIC, and substantially all of its assets were sold to JPMorgan Chase Bank, National Association. If other banks and financial institutions are similarly affected in the future in response to conditions affecting the banking system and financial markets, we may be unable to access and we may lose some or all of our cash and cash equivalents, which could have a material adverse effect on our operations.

### We are subject to governmental export and import controls that could impair our ability to compete in international markets or subject us to liability if we violate these controls.

Our products may be subject to U.S. export control laws and regulations including the Export Administration Regulations ("EAR") and trade and economic sanctions maintained by the Office of Foreign Assets Control ("OFAC"). As such, an export license may be required to export, reexport, or transfer our products to certain countries, end-users, and end-uses. If we were to fail to comply with such U.S. export controls laws and regulations, U.S. economic sanctions, or other similar laws, we could be subject to both civil and criminal penalties, including substantial fines, possible incarceration for employees and managers for willful violations, and the possible loss of our export or import privileges. Obtaining the necessary export license for a particular sale or offering may not be possible and may be time-consuming and may result in the delay or loss of sales opportunities. Furthermore, U.S. export control laws and economic sanctions prohibit the export of products to certain U.S. embargoed or sanctioned countries, governments, and persons, as well as for prohibited end-uses. Even though we take precautions to ensure that we and our partners comply with all relevant export



control laws and regulations, any failure by us or our partners, including third party manufacturers, to comply with such laws and regulations could have negative consequences for us, including reputational harm, government investigations and penalties.

Changes in our products or changes in export and import regulations in such countries may create delays in the introduction of our products into international markets, prevent our end-customers with international operations from deploying our products globally or, in some cases, prevent or delay the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws or regulations, economic sanctions or related legislation, shift in the enforcement or scope of existing export, import or sanctions laws or regulations, or change in the countries, governments, persons, or technologies targeted by such export, import or sanctions laws or regulations, could result in decreased use of our products by, or in our decreased ability to export or sell our products to, existing or potential end-customers with international operations. Any decreased use of our products or limitation on our ability to export to or sell our products in international markets could adversely affect our business, financial condition, and results of operations.

#### Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, collaboration, licensing agreement, product liability, employment, class action, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations.

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

As of December 31, 2022, we had federal net operating loss ("NOL") carryforwards totaling \$137.3 million. Of the \$137.3 million, \$109.0 million are carried forward indefinitely, but are subject to an 80% of taxable income limitation, and \$28.3 million which will begin to expire in 2033, if not utilized. As of December 31, 2022, we had state NOL carryforwards of \$64.6 million, which will begin to expire in 2035, if not utilized. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. As a result of previous transactions, including the Brookline Merger, we may have experienced such an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change NOL carryforwards and other pre-change taxable income or taxes may be subject to limitation.

#### Changes in tax law could materially impact our business, results of operations and financial condition.

Changes to U.S. federal, state, and local, and foreign tax laws, including those that may be enacted in the future could impact the tax treatment of our business operations. For example, the United States enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, the Organization for Economic Cooperation and Development has proposed a number of tax provisions that could impact our business if we expand internationally. Further, on January 1, 2022, a provision of the Tax Cuts and Jobs Act of 2017 went into effect that eliminates the option to deduct domestic research and development costs in the year incurred and instead requires taxpayers to amortize such costs over five years. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.



#### **Risks Related to Ownership of Our Common Stock**

### The price of shares of common stock may be volatile or may decline regardless of our operating performance. You may lose some or all of your investment.

The trading price of shares of our common stock is volatile. The stock market recently has experienced significant volatility. This volatility often has been unrelated or disproportionate to the operating performance of particular companies. You may not be able to resell your shares at an attractive price due to a number of factors such as those listed in *"Risks Related to Our Business, Financial Condition, and Need for Additional Capital"* and the following:

- the uncertainty surrounding our ability to continue as a going concern;
- our operating and financial performance and prospects;
- our quarterly or annual earnings or those of other companies in our industry compared to market expectations;
- conditions that impact demand for our products and/or services;
- future announcements concerning our business, our clients' businesses or our competitors' businesses;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- issuances, exchanges or sales, or expected issuances, exchanges or sales of our capital stock;
- changes in senior management or key personnel;
- the size of our public float;
- coverage by or changes in financial estimates by securities analysts or failure to meet their expectations;
- market and industry perception of our success, or lack thereof, in pursuing our growth strategy;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- changes in laws or regulations which adversely affect our industry or us;
- privacy and data protection laws and regulations, privacy or data breaches, or the loss of data;
- changes in accounting standards, policies, guidance, interpretations or principles;
- changes in general market, economic and political conditions in the United States and global economies or financial markets, including those resulting from the rising rate of inflation, natural disasters, terrorist attacks, acts of war and responses to such events.
- the impact of the COVID-19 pandemic on our financial condition and the results of operations;
- changes in our dividend policy;
- adverse resolution of new or pending litigation against us; and
- the market's reaction to our reduced disclosure and other requirements as a result of being an "emerging growth company" under the Jumpstart Our Business Startups Act (the "JOBS Act").

These broad market and industry factors may materially reduce the market price of shares of our common stock, regardless of our operating performance. In addition, price volatility may be greater if the public float and trading volume of our common stock is low. As a result, you may suffer a loss on your investment.

In the past, following periods of market volatility, stockholders have instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and the attention of executive management from our business regardless of the outcome of such litigation.

#### There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

The market price of our common stock has been volatile recently, trading below \$1.00 on certain days. If we do not maintain a stock price over \$1.00 per share for 30 consecutive business days, we would be at risk of delisting from the Nasdaq if we did not



regain compliance. If Nasdaq delists our shares from trading on its exchange for failure to maintain compliance with the bid-price-rule or otherwise meet the listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities trading on the over-the-counter market;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our common stock;
- a limited or no amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

### Certain of our warrants are accounted for as a warrant liability and are recorded at fair value upon issuance with changes in fair value each period reported in earnings, which may have an adverse effect on the market price of our common stock.

As of July 29, 2022, the closing date of the Brookline Merger, we had 123,500 private placement warrants outstanding, which became exercisable 30 days following the closing of the Brookline Merger. We may redeem outstanding warrants in certain circumstances. Under GAAP, we are required to evaluate contingent exercise provisions of these warrants and then their settlement provisions to determine whether they should be accounted for as a warrant liability or as equity. Any settlement amount not equal to the difference between the fair value of a fixed number of our equity shares and a fixed monetary amount precludes these warrants from being considered indexed to its own stock, and therefore, from being accounted for as equity. As a result of the provision that the private placement warrants, when held by someone other than the initial purchasers or their permitted transferees, will be redeemable by us, the requirements for accounting for these warrants as equity are not satisfied. Therefore, we are required to account for these private placement warrants as a warrant liability and record (a) that liability at fair value, and (b) any subsequent changes in fair value as of the end of each period for which earnings are reported. The impact of changes in fair value on earnings may have an adverse effect on the market price of our common stock.

#### Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud.

Prior to the Brookline Merger, our predecessor, BCAC, had identified a material weakness in its internal controls over financial reporting in connection with the reclassification of the warrants. The material weakness was remediated in 2022. If we identify further material weaknesses in our internal control over financial reporting, any such identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim consolidated financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses.

#### We do not intend to pay dividends on shares of our common stock for the foreseeable future.

We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, we do not anticipate declaring or paying any cash dividends on shares of our common stock in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our Board and will depend on, among other things, our business prospects, results of operations, financial condition, cash requirements and availability, certain restrictions related to our indebtedness, industry trends and other factors that our Board may deem relevant. Any such decision will also be subject to compliance with contractual restrictions and covenants in the agreements governing our current and future indebtedness. In addition, we may incur additional indebtedness, the terms of which may further restrict or prevent us from paying dividends on our common stock. As a result, you may have to sell some or all of your shares of our common stock after price appreciation in order to generate cash flow from your investment, which you may not be able to do. Our inability or decision not to pay dividends, particularly when others in our industry have elected to do so, could also adversely affect the market price of shares of our common stock.

### If securities analysts do not publish research or reports about us, or if they issue unfavorable commentary about us or our industry or downgrade our common stock, the price of shares of our common stock could decline.

The trading market for shares of our common stock will depend in part on the research and reports that third-party securities analysts publish about us and the industries in which we operate. We may be unable or slow to attract research coverage and if one or more analysts cease coverage of us, the price and trading volume of our securities would likely be negatively impacted. If any of the analysts that may cover us change their recommendation regarding our securities adversely, or provide more favorable relative recommendations about our competitors, the price of our securities would likely decline. If any analyst that may cover us ceases covering us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the price or trading volume of our securities to decline. Moreover, if one or more of the analysts who cover us downgrades our common stock, or if our reporting results do not meet their expectations, the market price of shares of our common stock could decline.

### Our issuance of additional shares of common stock could make it difficult for another company to acquire us, may dilute your ownership of us and could adversely affect our stock price.

We filed a registration statement with the SEC on Form S-8 providing for the registration of shares of our common stock issued or reserved for issuance under our 2020 Equity Incentive Plan, 2022 Equity Incentive Plan and 2022 ESPP. Subject to the satisfaction of vesting conditions and the expiration of any applicable lockup agreements, shares registered under the registration statement on Form S-8 are available for resale immediately in the public market without restriction. In addition, under our purchase agreement dated March 17, 2022 with Lincoln Park (the "equity line agreement"), we have the right to direct Lincoln Park to purchase an aggregate of up to \$50,000,000 of our common stock from time to time, subject to certain limitations. As of June 30, 2023, we have issued 1,266,684 shares of our common stock under the equity line agreement, including 150,000 on July 29, 2022, 500,000 shares of our common stock 90 calendar days after July 29, 2022 and 616,684 shares of common stock pursuant to purchases we directed under the equity line agreement.

On January 30, 2023, we completed a private placement, issuing an aggregate of 1,995,708 shares of common stock and accompanying warrants to purchase the same number of shares, for approximately \$2.8 million. From time to time in the future, we may issue additional shares of common stock or securities convertible into common stock pursuant to a variety of transactions, including acquisitions. The issuance by us of additional shares of common stock or securities convertible into common stock would dilute your ownership of us and the sale of a significant amount of such shares in the public market could adversely affect prevailing market prices of shares of our common stock.

In the future, we expect to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including senior or subordinated notes, debt securities convertible into equity, or shares of preferred stock. Issuing additional shares of our common stock, other equity securities, or securities convertible into equity may dilute the economic and voting rights of our existing stockholders, reduce the market price of shares of our common stock, or both. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred stock, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offerings. As a result, holders of our common stock bear the risk that our future offerings may reduce the market price of shares of our common stock and dilute their percentage ownership.



### Sales of our common stock, or the perception of such sales, by us or our existing stockholders in the public market could cause the market price for our common stock to decline and certain Selling Securityholders still may receive significant proceeds.

The sale of substantial amounts of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our common stock may cause the trading price of our securities to drop significantly.

All shares issued as merger consideration in the Brookline Merger are freely tradable without registration under the Securities Act and without restriction by persons other than our "affiliates" (as defined under Rule 144), including our directors, executive officers and other affiliates, and certain other former Legacy Apexigen stockholders.

Shares held by certain of our stockholders are eligible for resale, subject to, in the case of certain stockholders, volume, manner of sale and other limitations under Rule 144. In addition, pursuant to the Registration Rights and Lock-Up Agreement that we entered into with certain stockholders in connection with the Brookline Merger, we registered the sale of their shares of common stock under the Securities Act, and pursuant to the Registration Rights Agreement that we entered into with Lincoln Park, we registered the shares of our common stock issued to Lincoln Park pursuant to the equity line agreement under the Securities Act.

Further, shares held by our stockholders who participated in our private placement in January 2023 will be eligible for resale, subject to applicable resale restrictions, and following the effectiveness of the resale registration statement we are obligated to file for such stockholders.

As restrictions on resale end or if these stockholders exercise their registration rights, the market price of shares of our common stock could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of shares of our common stock or other securities.

In addition, the shares of our common stock reserved for future issuance under the 2022 Plan and 2022 ESPP will become eligible for sale in the public market as those shares are issued, subject to provisions relating to various vesting agreements, and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable.

#### Our management team has limited experience in operating a public company.

Our executive officers have limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage its transition to a public company that will be subject to significant regulatory oversight and reporting obligations under federal securities laws. For example, we failed to timely file our Form 10-Q for the quarter ended June 30, 2022. Their limited experience in dealing with the increasingly complex laws pertaining to public companies could be a significant disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities which will result in less time being devoted to the management and growth of the company. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices or internal controls over financial reporting required of public companies in the United States. The development and implementation of the standards and controls necessary for us to achieve the level of accounting standards required of a public company in the United States may require costs greater than expected. It is possible that we will be required to expand our employee base and hire additional employees to support our operations as a public company which will increase our operating costs in future periods.

### As a public reporting company, we are subject to rules and regulations established from time to time by the SEC regarding our internal control over financial reporting.

We are a public reporting company subject to the rules and regulations established from time to time by the SEC and Nasdaq. These rules and regulations require, among other things that we establish and periodically evaluate procedures with respect to our internal control over financial reporting. Reporting obligations as a public company are likely to place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel.

In addition, as a public company, we are required to document and test our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act so that our management can certify as to the effectiveness of our internal control over financial reporting. The design of our internal controls over financial reporting post-Brookline Merger has required and will continue to require significant time and resources from management and other personnel. As a result, management was unable, without incurring unreasonable effort or expense, to conduct an assessment of our internal control over financial reporting as of June 30, 2023. Accordingly, we are excluding management's report on internal control over financial reporting in this Quarterly Report on Form 10-Q pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations.



If we are not able to implement the requirements of Section 404, including any additional requirements once we are no longer an emerging growth company, in a timely manner or with adequate compliance, we may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our common stock.

Additionally, once we are no longer an emerging growth company, we will be required to comply with the independent registered public accounting firm attestation requirement on our internal control over financial reporting. We will be an "emerging growth company" until the earlier of (1) the last day of the fiscal year (a) following February 2, 2026, the fifth anniversary of the BCAC IPO, (b) in which we have total annual gross revenue of at least \$1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our prior second fiscal quarter, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. Until we cease being an emerging growth company stockholders will not have the benefit of an independent assessment of the effectiveness of our internal control environment.

#### As an "emerging growth company," we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

As an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to obtain an assessment of the effectiveness of our internal controls over financial reporting from our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. 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, which we have elected to do.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active market for our common stock, our share price may be more volatile and the price at which our securities trade could be less than if we did not use these exemptions.

### Anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of us more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our Board. Among other things, our amended and restated certificate of incorporation and/or bylaws include the following provisions:

- a staggered board, which means that our Board is classified into three classes of directors with staggered three-year terms and directors are only able to be removed from office for cause;
- limitations on convening special stockholder meetings, which could make it difficult for our stockholders to adopt desired governance changes;
- a prohibition on stockholder action by written consent, which means that our stockholders are only be able to take action at a meeting of stockholders and are not able to take action by written consent for any matter;
- a forum selection clause, which means certain litigation against us can only be brought in Delaware;
- the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without further action by our stockholders; and
- advance notice procedures, which apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.



These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents interested stockholders, such as certain stockholders holding more than 15% of our outstanding common stock, from engaging in certain business combinations unless (i) prior to the time such stockholder became an interested stockholder, the Board approved the transaction that resulted in such stockholder, the interested stockholder, (ii) upon consummation of the transaction that resulted in such stockholder becoming an interested stockholder owned at least 85% of the common stock, or (iii) following Board approval, such business combination receives the approval of the holders of at least two-thirds of our outstanding common stock not held by such interested stockholder.

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

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

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the (i) Court of Chancery (the "Chancery Court") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (A) any derivative action, suit or proceeding brought on our behalf; (B) any action, suit or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers, or stockholders to us or to our stockholders; (C) any action, suit or proceeding asserting a claim arising pursuant to the DGCL, the our amended and restated charter or our amended and restated bylaws; or (D) any action, suit or proceeding asserting a claim governed by the internal affairs doctrine; and (ii) subject to the foregoing, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Notwithstanding the foregoing, such forum selection provisions shall not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts of the United States have exclusive jurisdiction. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Additionally, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As noted above, our amended and restated bylaws provide that the federal district courts of the United States of America shall have jurisdiction over any action arising under the Securities Act. Accordingly, there is uncertainty as to whether a court would enforce such provision. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

None.

#### Item 3. Defaults Upon Senior Securities.

None.

#### Item 4. Mine Safety Disclosures.

Not applicable.

#### Item 5. Other Information.

None.

#### Item 6. Exhibits.

| Exhibit<br>Number | Description   |
|-------------------|---|
| 2.1+              | Agreement and Plan of Merger, dated May 23, 2023, by and among Pyxis Oncology, Inc., Ascent Merger Sub Corp. and Apexigen, Inc.           |
|                   | (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by the Company on May 24, 2023).                        |
| 10.1              | Form of Voting Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company on May 24,     |
|                   | <u>2023).</u>   |
| 31.1*             | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as      |
|                   | Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2*             | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as      |
|                   | Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 32.1*†            | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley |
|                   | <u>Act of 2002.</u>   |
| 32.2*†            | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley |
|                   | <u>Act of 2002.</u>   |
| 101.INS           | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded         |
|                   | within the Inline XBRL document.  |
| 101.SCH           | Inline XBRL Taxonomy Extension Schema Document  |
| 101.CAL           | Inline XBRL Taxonomy Extension Calculation Linkbase Document  |
| 101.DEF           | Inline XBRL Taxonomy Extension Definition Linkbase Document   |
| 101.LAB           | Inline XBRL Taxonomy Extension Label Linkbase Document  |
| 101.PRE           | Inline XBRL Taxonomy Extension Presentation Linkbase Document   |
| 104               | Cover Page Interactive Data File (embedded within the Inline XBRL document)   |

+ Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Apexigen hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that Apexigen may request confidential treatment pursuant to Rule 24b-20f the Exchange Act for any exhibits or schedules so furnished.

<sup>†</sup> The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

<sup>\*</sup> Filed herewith.

#### 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.

|                       | Apexigen, Inc.                               |
|-----------------------|--|
| Date: August 10, 2023 | By: /s/ Xiaodong Yang                        |
|                       | Xiaodong Yang, M.D., Ph.D.                   |
|                       | Chief Executive Officer                      |
|                       | (Principal Executive Officer)                |
|                       |  |
| Date: August 10, 2023 | By: /s/ William Duke, Jr.                    |
|                       | William Duke, Jr.                            |
|                       | Chief Financial Officer                      |
|                       | (Principal Financial and Accounting Officer) |
|                       |  |
|                       |  |

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

I, Xiaodong Yang, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 of Apexigen, 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.

#### Apexigen, Inc.

Date: August 10, 2023

By: /s/ Xiaodong Yang

Xiaodong Yang, M.D., Ph.D. Chief Executive Officer (Principal Executive Officer)

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

I, William Duke, Jr., certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 of Apexigen, 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.

#### Apexigen, Inc.

Date: August 10, 2023

By: /s/ William Duke, Jr.

William Duke, Jr. Chief Financial Officer (Principal Financial and Accounting Officer)

#### 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 Apexigen, Inc. (the "<u>Company</u>") on Form 10-Q for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "<u>Report</u>"), I, Xiaodong Yang, Chief Executive Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 10, 2023

By: /s/ Xiaodong Yang

Xiaodong Yang, M.D., Ph.D. Chief Executive Officer (Principal Executive Officer)

#### 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 Apexigen, Inc. (the "<u>Company</u>") on Form 10-Q for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "<u>Report</u>"), I, William Duke, Jr., Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 10, 2023

By: /s/ William Duke, Jr.

William Duke, Jr. Chief Financial Officer (Principal Financial and Accounting Officer)