As filed with the Securities and Exchange Commission on August 28, 2026.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware
(State or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code Number)

42-1977778
(I.R.S. Employer Identification Number)

1030 Massachusetts Avenue
Cambridge, MA 02138
(781) 806-6245
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Madan Jagasia
Chief Executive Officer
1030 Massachusetts Avenue
Cambridge, MA 02138
(781) 806-6245
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Cambridge, MA 02138
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Approximate Date of Commencement of Proposed Sale to the Public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

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

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

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

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller Reporting Company	☐
		Emerging Growth Company	☒

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

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

EXPLANATORY NOTE

On August 3, 2026, or the Closing Date, Obsidian Therapeutics, Inc., a Delaware corporation (formerly known as Gazelle Parent, Inc.), or the Parent (also referred to herein as "we" or "us"), completed the previously announced Mergers (as defined below) pursuant to the Agreement and Plan of Merger, dated April 14, 2026, or the Merger Agreement, by and among Parent, Obsidian Therapeutics Sub, Inc., a Delaware corporation, (formerly known as Obsidian Therapeutics, Inc., or Legacy Obsidian), Onyx MergerSub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Parent, or Obsidian Merger Sub, Galera Therapeutics, Inc., a Delaware corporation, or Legacy Galera, and Gazelle Merger Subsidiary, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Parent, or Galera Merger Sub. On the Closing Date, pursuant to the Merger Agreement and on the terms and conditions set forth therein, each pursuant to the provisions of the General Corporation Law of the State of Delaware, as amended, or the DGCL, (a) Obsidian Merger Sub merged with and into Legacy Obsidian, with Legacy Obsidian as the surviving entity, which transaction is referred to herein as the "Obsidian Merger," and (b) immediately following the Obsidian Merger, Galera Merger Sub merged with and into Legacy Galera, with Legacy Galera as the surviving entity, which transaction is referred to herein as the "Galera Merger," and together with the Obsidian Merger, referred to herein as the "Mergers."

Concurrently with entering into the Merger Agreement, on April 14, 2026, Legacy Obsidian and Legacy Galera entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain qualified institutional buyers and/or accredited investors, or the Investors. Pursuant to the Securities Purchase Agreement, and subject to the terms and conditions therein, the Investors agreed to purchase, and Legacy Galera agreed to issue and sell, immediately prior to the effective time of the Obsidian Merger, or the Obsidian Effective Time, shares of Legacy Galera's Series C Non-Voting Convertible Preferred Stock, par value $0.001 per share, or Series C Preferred Stock, for an aggregate purchase price of $350.0 million, or the PIPE Financing. On the Closing Date, each outstanding share of Legacy Galera common stock (including those resulting from the conversion of the preferred stock and pre-funded warrants, but excluding dissenting shares and certain excluded shares as described in the prospectus filed by the Parent on July 2, 2026) was converted into the right to receive a number of shares of common stock of Parent, par value $0.0001 per share, or Parent Common Stock, calculated as described in the prospectus filed by the Parent on July 2, 2026.

Our common stock began trading on the Nasdaq Capital Market, or Nasdaq, under the symbol "OBX" on August 4, 2026.

Subject to Completion, Dated August 28, 2026

PRELIMINARY PROSPECTUS

OBSIDIAN THERAPEUTICS

29,164,045 Shares of Common Stock

This prospectus relates to the proposed offer and resale or other disposition from time to time by the selling stockholders identified in this prospectus of up to an aggregate of 29,164,045 shares of our common stock, par value $0.0001 per share.

We are registering the resale of the shares of common stock pursuant to the selling stockholders' registration rights under a registration rights agreement between us and the selling stockholders. Our registration of the resale of the shares of common stock covered by this prospectus does not mean that the selling stockholders will offer or sell all or any of the shares of common stock. The selling stockholders may offer, sell or distribute all or a portion of their shares of common stock from time to time directly or indirectly through one or more underwriters, broker-dealers or agents, and in one or more public or private transactions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. See the section titled "*Plan of Distribution*" for more information.

We will not receive any proceeds from any sale of common stock by the selling stockholders pursuant to this prospectus. We have agreed to bear the expenses in connection with the registration of the resale of the shares of common stock to be offered by this prospectus by the selling stockholders other than any underwriting discounts and commissions or transfer taxes relating to the sale of common stock, which will be borne by the selling stockholders.

Our common stock is listed on Nasdaq under the symbol "OBX." On August 27, 2026, the closing price for our common stock, as reported on Nasdaq, was $17.04 per share.

See the section titled "Risk Factors" beginning on page 9 of this prospectus to read about factors you should consider before buying our securities.

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

The date of this prospectus is , 2026.

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You should rely only on the information provided in this prospectus, as well as the information incorporated by reference in the exhibits to the registration statement of which this prospectus forms a part and any applicable prospectus supplement or amendment. Neither we nor the Selling Stockholders have authorized anyone to provide you with different information. Neither we nor the Selling Stockholders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date of the applicable document. Since the date of this prospectus and the documents filed as exhibits to the registration statement of which this prospectus forms a part, our business, financial condition, results of operations and prospects may have changed.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1, or the Registration Statement, that we filed with the Securities and Exchange Commission, or the SEC, using the "shelf" registration process, and relates to the resale by the selling stockholders identified in this prospectus under the caption "*Selling Stockholders*," from time to time, of up to an aggregate of 29,164,045 shares of our common stock. We are not selling any shares of common stock under this prospectus, and we will not receive any proceeds from the sale of shares of common stock offered hereby by the Selling Stockholders.

We have not authorized anyone to provide you with information other than the information that we have provided in this prospectus and your reliance on any unauthorized information or representation is at your own risk. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus and that any information in a supplement or amendment to this prospectus is accurate only as of the date of such supplement or amendment. Our business, financial condition, results of operations and prospects may have changed since those dates.

MARKET AND INDUSTRY DATA

Neither we, nor the selling stockholders, have authorized anyone to give any information or to make any representation other than those contained in this prospectus. You must not rely upon any information or representation not contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any shares other than the registered shares to which it relates, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy shares in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front of the document even though this prospectus is delivered or shares are sold on a later date. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus includes market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included in this prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" contained in this prospectus. Accordingly, investors should not place undue reliance on this information.

A prospectus supplement may add to, update or change the information contained in this prospectus. You should read both this prospectus and any applicable prospectus supplement together with additional information described below under the heading "*Where You Can Find More Information*".

TRADEMARKS

Unless the context otherwise indicates, references in this prospectus to "Company," "we," "our" and "us" refer collectively to Obsidian Therapeutics, Inc., a Delaware corporation, and its consolidated subsidiaries (including Legacy Obsidian).

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus. Unless the context otherwise requires, the terms "Obsidian," the "Company," "we," "us," and "our" in this prospectus refer to Obsidian Therapeutics, Inc. (or the Parent) and its wholly owned subsidiaries, as the context may require.

Overview

We are a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor infiltrating lymphocyte, or TIL, cell therapies for the treatment of patients with solid tumors. Our proprietary cytoDRiVE™ platform is highly versatile and allows us to leverage drug responsive domains, or DRDs, to control protein function, with our initial focus on TIL cell therapies developed from this platform, or cytoTILs™. Our lead product candidate, amsoki-cel (formerly, "OBX-115"), is a novel, genetically engineered, autologous TIL cell therapy currently in a Phase 2 clinical trial for the treatment of advanced melanoma and a Phase 1 clinical trial for the treatment of non-small cell lung cancer, or NSCLC. Our proprietary cytoDRiVE platform has enabled amsoki-cel to have the potential to drive superior tumor-killing activity with a significantly more tolerable safety profile. In contrast to other TIL approaches, amsoki-cel is designed with regulatable membrane-bound IL15, or mbIL15, which drives TIL persistence, eliminates the need to dose toxic interleukin-2, or IL2, and enables outpatient administration of low-dose lymphodepletion. We currently own or in-license the intellectual property rights to amsoki-cel and own the intellectual property to our proprietary cytoDRiVE platform. Furthermore, amsoki-cel can be manufactured using tumor tissue procurement from an outpatient, minimally invasive core needle biopsy. Across a cohort of fifteen patients with treatment-resistant or refractory melanoma in our Phase 1/2 clinical trial, amsoki-cel administration at the recommended Phase 2 dose demonstrated a 67% confirmed objective response rate, or ORR, and significant tumor burden reduction, including two confirmed complete responses, or CRs. This response rate, to our knowledge, is the highest current ORR shown in this setting across modalities. We believe that, if approved, the more favorable product profile will support rapid market adoption of amsoki-cel relative to currently available TIL cell therapies. Amsoki-cel has been granted Fast Track and Regenerative Medicine Advanced Therapy, or RMAT, designations from the U.S. Food and Drug Administration, or FDA, for the treatment of patients with unresectable or metastatic melanoma that is resistant to immune checkpoint inhibitor, or ICI, therapy. These designations are advantageous to facilitate and expedite the review of therapies, allow for more frequent meetings with FDA to discuss the development plan for the product candidate, and enable potential eligibility for rolling review and priority review, however such designations do not guarantee marketing approval, either on an accelerated basis or otherwise. In our Phase 1 clinical trial in NSCLC, early clinical results show robust tumor shrinkage and include multiple confirmed partial responses, or PRs. We expect to present updated melanoma RP2D data in the fourth quarter of 2026, followed by additional NSCLC Phase 1 clinical data in the first half of 2027 and topline data from our melanoma registration-enabling cohort by year-end 2027. We believe our product candidates are distinct from current cell therapies and have the potential to significantly impact the treatment of solid tumors and clinical outcomes of patients with cancer.

Cell therapies have delivered transformational benefits in treating hematological malignancies; however, their impact in treating solid tumors has been limited. Approved chimeric antigen receptor, or CAR-T, cell therapies or engineered T-cell receptor, or TCR-T, cell therapies, which target single antigens, have demonstrated limited efficacy in solid tumors while leading to significant toxicities. Solid tumors present formidable barriers to immune and cell therapies, including antigen heterogeneity, physical exclusion of immune cells, immunosuppressive tumor microenvironments, and adverse effects due to overlapping expression of tumor targets in tumor cells with non-tumor host cells. Furthermore, while immunotherapies such as ICIs have improved outcomes for patients, more

than 85% of cancer patients fail to respond to ICI therapy. As such, solid tumors represent an area of high unmet clinical need, accounting for over 90% of cancer deaths.

We believe that by using TIL, which are immune cells extracted from a patient's own tumor, and our cytoDRiVE platform to develop amsoki-cel, we will be able to overcome the challenges faced by traditional cell therapies. As TIL contain T cells that recognize a broad spectrum of tumor antigens, the potential for loss of antitumor activity due to antigen heterogeneity is limited. In addition, TIL, being tumor-derived, has an advantage over T cell therapies manufactured from circulating T cells based on their ability to migrate to tumors.

Clinical trials with standard non-engineered TIL, the first generation of TIL cell therapy that involves isolation and expansion of all TIL in the tumor sample, have shown objective responses in clinical trials in limited solid tumor types. Amsoki-cel is an engineered TIL expressing pharmacologically regulatable mbIL15, which has been shown to enhance their cytotoxicity and potentially their persistence.

We have a growing library of internally discovered DRDs of varying sizes and purposes, and our cytoDRiVE platform is designed to enable rapid optimization of tunable and functional proteins. We have developed an extensive synthetic biology engineering toolkit to potentially optimize protein functionality in any cell type, including but not limited to, type I/II membrane proteins, membrane-tethered cytokines, intracellular proteins, secreted proteins, and genome editing proteins. In addition to the development of our cytoTILs, we are exploring the breadth of our cytoDRiVE platform by developing novel approaches that expand its potential applications to additional cell therapies, including the ability to regulate secreted proteins and expression of messenger RNA, or mRNA, or small interfering RNA, or siRNA. cytoDRiVE is highly versatile and can be applied across a broad range of therapeutic applications, including to broaden the reach of cell therapies (including CAR-T) and gene therapies outside of oncology. Our cytoDRiVE platform has led to the development of our lead cytoTIL product candidate, amsoki-cel, with carbonic anhydrase 2, or CA2, as the DRD which is pharmacologically regulated by acetazolamide, or ACZ, to allow for control of mbIL15 expression.

Our Strategy

Our goal is to leverage our cytoDRiVE platform to unlock the full potential of cell therapies to treat solid tumors. We believe that our ability to dynamically regulate the activity of our cell therapies in the body using our cytoDRiVE platform is key to achieving this goal. Our strategy is as follows:

- Advance amsoki-cel for the treatment of melanoma and NSCLC. Clinical results in patients with second-line advanced melanoma previously treated with ICI therapy provide compelling support for the differentiated antitumor and tolerability profile of amsoki-cel. We expect to present updated melanoma RP2D data in the fourth quarter of 2026. Enrollment is ongoing in our registration-enabling cohort of our existing multicenter Agni-01 study for amsoki-cel in second-line advanced melanoma, with topline data expected by year-end 2027. A registration-enabling study is a clinical trial that is intended to obtain sufficient efficacy and safety data to support an NDA or BLA submission to obtain regulatory approval. Although registration-enabling clinical studies are often Phase 3 trials, the FDA has approved drugs based on Phase 2 registration-enabling clinical studies through its accelerated approval program, provided the product is eligible and meets the conditions of accelerated approval. We are also investigating the potential of amsoki-cel as a first-line treatment for advanced melanoma in a dedicated cohort of our ongoing Agni-01 multicenter study. In NSCLC, early clinical results in patients previously treated with ICIs suggest that amsoki-cel has the potential to deliver meaningful antitumor activity in NSCLC while maintaining a generally well-tolerated profile. We intend to continue enrolling patients in our ongoing trial and expect Phase 1 clinical data in the first half of 2027. Similar to melanoma, we believe that the observed tolerability profile of amsoki-cel may provide an opportunity to evaluate the potential of amsoki-cel earlier in the course of disease.
- Evaluate the potential of amsoki-cel for the treatment of other solid tumors. Amsoki-cel may be applicable to additional solid tumor types where scientific rationale or prior TIL activity supports development, including tumors with prognostic TIL associations, supportive preclinical findings, or

clinical responses to non-engineered TIL. This rationale extends to tumor types with FDA approved ICI therapies, where endogenous TIL activity is a mediator of response and progression following ICI therapy may indicate exhaustion of TIL function. By leveraging cytoDRiVE and our proprietary manufacturing process, in contrast to what is currently feasible with non-engineered TIL, amsoki-cel may be manufactured from these tumors, whether they harbor suppressed tumor reactive TIL that regulatable mbIL15 may functionally enhance or fewer TIL overall that are potentially expandable in the REP phase leading to robust cell dose yields.

- Advance our manufacturing capabilities in anticipation of our biologics license application, or BLA, and, if approved, commercial launch. We believe our proprietary manufacturing process enables advantages in phenotype, yield, process robustness, and tumor procurement flexibility. We collaborate with leading contract development manufacturing organizations, or CDMOs, with cell therapies expertise to manufacture amsoki-cel, and plan to expand our capacity with these partners as we approach potential regulatory approval.
- Commercialize amsoki-cel in the United States and evaluate partnership opportunities in other regions. We intend to retain commercial rights to amsoki-cel in the United States and opportunistically evaluate strategic collaborations to maximize the commercial potential of amsoki-cel in other regions.
- Continue to invest in our cytoDRiVE platform and intellectual property for our cytoTIL product candidates while actively exploring strategic partnerships and collaborations for other applications of our platform. Our cytoDRiVE platform is designed to be highly versatile and fit-for-purpose, with the ability to drive on- or off-activity across multiple classes of proteins and cell types. We believe there are potential next-generation applications across oncology and broader therapeutic areas. This abundance of potential treatment opportunities may enable us to selectively enter strategic collaborations involving our cytoDRiVE platform to maximize the patient benefit and long-term value of our research and development portfolio.

Our Pipeline

We are building an innovative pipeline of genetically engineered TIL cell therapies, led by amsoki-cel, for the treatment of solid tumors. We own worldwide rights to amsoki-cel and our earlier stage product candidates. Our current pipeline is summarized in the diagram below.

Summary of Material Risks Associated with our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company and have incurred significant financial losses since inception and anticipate that we will continue to incur significant financial losses for the foreseeable future. We may never achieve or maintain profitability.

- If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.
- Raising additional capital may cause dilution to our stockholders, restrict operations, or require us to relinquish rights to our product candidate.
- Our business is highly dependent on the success of our product candidate, amsoki-cel. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize our product candidate, or if we experience delays in doing so, our business will be materially harmed.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators, CROs and contract development manufacturing organizations, or CDMOs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our current and future product candidates and our business could be substantially harmed.
- If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled "*Risk Factors*" and the other information set forth in this prospectus, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission, or the SEC. The risks summarized above or described in full elsewhere in this prospectus are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future, growth prospects.

Corporate History

Our principal corporate office is located at 1030 Massachusetts Avenue, Cambridge, MA 02138, and our telephone number is (781) 806-6245. Our website address is *www.obsidiantx.com*. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. Our common stock is listed on Nasdaq Capital Market under the symbol "OBX."

Implications of Being an Emerging Growth Company

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

- being permitted to present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;

- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of the Mergers; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of these elections, the information that we provide in this prospectus including our financial statements, may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

THE OFFERING

Issuer	Obsidian Therapeutics, Inc.
Common stock Offered by the Selling Stockholders	29,164,045 shares of common stock
Use of Proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus. See the section titled "*Use of Proceeds*" appearing elsewhere in this prospectus for more information.
Nasdaq Symbol	"OBX."
Offering Price	The selling stockholders will offer the shares of common stock offered by this prospectus at the prevailing market prices or at privately negotiated prices.
Risk Factors	You should read the "*Risk Factors*" section of this prospectus beginning on page 9 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

For additional information concerning the offering, see "*Plan of Distribution*" beginning on page 166.

RISK FACTORS

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Special Note Regarding Forward-Looking Statements," you should carefully consider the specific risks set forth herein. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto, and the other financial information concerning us included elsewhere in this prospectus. Additionally, the risks and uncertainties described in this prospectus or any prospectus supplement are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risks Related to Our Financial Condition, Need for Additional Capital and Manufacturing and Commercialization Efforts

We are a clinical-stage biopharmaceutical company and have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future. We may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history and have incurred losses since our inception. Our operations to date have been limited to pre-commercial activities. We have not yet demonstrated an ability to generate revenue, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We will encounter risks and difficulties frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidate.

We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance our product candidate through clinical development, including conducting our ongoing clinical trials;
- seek regulatory approvals for our product candidate or any future product candidates that successfully complete clinical trials;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical and preclinical development, manufacturing and commercialization efforts;
- undertake any pre-commercial or commercial activities to establish sales, marketing, and distribution capabilities;
- advance any future product candidates into clinical development;
- seek to identify, acquire, and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;

- maintain, expand, and protect our intellectual property portfolio;
- make milestone, royalty, or other payments due under our license and collaboration agreements and any future license, collaboration or other agreements;
- make milestone, royalty, interest, or other payments due under any future financing or other arrangements with third parties;
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company;
- establish or work with third-parties to establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize any product candidates for which we may obtain regulatory approval; and
- add equipment and physical infrastructure to support our research and development.

Biopharmaceutical product development entails substantial up-front capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement, or become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays, and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other comparable regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of our product candidate or any future product candidates.

We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical 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 continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, our product candidate. Even if our current or future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our operations principally through private financings. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical and preclinical development of our product candidate, commence additional preclinical studies and clinical trials, and continue to identify and develop additional product candidates either through internal development or through acquisitions or in-licensing product candidates.

As of June 30, 2026, we had cash and cash equivalents and marketable securities of $34.4 million. Based upon our current operating plans, we believe that the net proceeds from the PIPE financing, together with our existing cash and cash equivalents and short-term investments in marketable securities, will be sufficient to fund our operations into the second half of 2028.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We may also raise additional financing on an opportunistic basis in the future. For example, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidate. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing, and outcome of regulatory review of our current or any future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies, or assets, including the timing and amount of any milestones, royalties, or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effectiveness of our approach at identifying target patient populations and utilizing our approach to enrich our patient population in our clinical trials;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for our product candidate or any future product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidate or any future product candidates for which we receive marketing approval;
- expenses to attract, hire, and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation, tariffs, and interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products, and technologies.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for our product candidate, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, we expect to incur additional costs associated with

operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political, and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce, or terminate our product development programs, future commercialization efforts, or other operations.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash, cash equivalents, and marketable securities, the net proceeds from the Mergers and the PIPE Financing, any future equity or debt financings, and upfront and milestone and royalties payments, if any, received under any future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt securities, or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or acquiring, selling, or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

Risks Related to Our Business Operations and Industry

Our business is highly dependent on the success of our product candidate, amsoki-cel. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize our product candidate, or if we experience delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidates and our current product candidate remains in clinical development. Our future success and ability to generate revenue from our product candidate is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize our product candidate or any future product candidate. Our product candidate and any future product candidates will require substantial additional investment for clinical development, regulatory review, and approval in one or more jurisdictions. If our product candidate or any future product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidate, including:

- our ability to demonstrate to the satisfaction of the FDA, EMA, or other comparable regulatory authorities that our product candidate is safe and effective for one or more intended uses;
- the sufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies, or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidate;
- delays in submitting an Investigational New Drug application, or IND, or other regulatory submission to the FDA, EMA, or other comparable regulatory authorities, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension, termination, or hold, of a clinical trial once commenced, including any delays caused by prolonged government shutdowns, inadequate funding, loss of employees, changes in regulations, leadership, or policies by a new administration or other disruptions of regulatory authorities;
- conditions imposed by the FDA, the EMA, or other comparable regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidate during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in recruiting or enrolling subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of our product candidate or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA, or other comparable regulatory authority inspections and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise to meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies, leadership, and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our investigational therapies in particular; or
- varying interpretations of data by the FDA, EMA, and other comparable regulatory authorities.

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

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current or future product candidates may face competition from major pharmaceutical companies, specialty pharmaceutical companies, universities, and other research institutions and from products and therapies that currently exist or are being developed, some of which products and therapies we may not currently know about.

Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical, and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients, and manufacturing pharmaceutical products, and they may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel cell therapies or to in-license novel cell therapies that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA or other regulatory approval or discovering, developing, and commercializing products in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Our competitors may obtain FDA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Our competitors may also develop cell therapies or other platform technologies that are more effective, more convenient, more widely used, or less costly than our product candidate or, in the case of drugs, have a better safety profile than our product candidate. These competitors may also be more successful than us in manufacturing and marketing their products and have significantly greater financial resources and expertise in research and development.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. We may compete with other cell therapy or immunotherapy companies such as Iovance Biotherapeutics Inc., Replimune Group Inc., AbelZeta Inc., Biosyngen Pte Ltd, GRIT Biotechnology Co., Ltd., Shanghai Juncell Therapeutics Co., Ltd., Immatics N.V., Immunocore Holdings plc, Intima Bioscience, Inc., KSQ Therapeutics, Inc., Marker Therapeutics, Inc., TILT Biotherapeutics Ltd, and others. In addition, numerous compounds are in clinical development for cancer treatment. Many of these companies are well-capitalized and have significant clinical experience.

Smaller and other early-stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our current and any future product candidates. In addition, the biopharmaceutical 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 product candidates obsolete, less competitive, or not economical.

Universities and public and private research institutions in the United States and Europe are also potential competitors. For example, a Phase 3 M14TIL clinical trial compared TIL to standard ipilimumab in patients with metastatic melanoma was conducted in Europe by the Netherlands Cancer Institute, the Copenhagen County Herlev University Hospital, and the University of Manchester. Results from the M14TIL clinical trial were presented at the European Society for Medical Oncology Congress in September 2022 and were subsequently published. In patients with advance melanoma, progression-free survival was significantly longer among those who received TIL cell therapy than among those who received ipilimumab. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our technologies and products.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed, or are less expensive than any products that we may develop. Even if our product candidates achieve marketing approval, they may be priced at a significant

premium over competitive products if any, which have been approved by then, resulting in reduced competitiveness. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become and remain profitable.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Our lead product candidate, amsoki-cel, is currently in Phase 2 clinical development for the treatment of advanced melanoma and is currently in Phase 1 clinical development for the treatment of non-small cell lung cancer, or NSCLC, and our other product candidates and programs are at various stages of preclinical development. We seek to develop engineered TIL cell therapies for the treatment of patients with solid tumors.

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

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products, or technologies, through the licensing of products or technologies from third parties or other strategic alliances. The failure to manage acquisitions, investments, licenses, or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies, and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in, or license other technologies, products, and businesses that may enhance our capabilities, complement our existing products and technologies, or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses, and other alliances involve numerous risks, including difficulty integrating acquired or licensed technologies, products, employees, or business operations, unanticipated costs associated with acquisitions or strategic alliances, and diversion of management's attention from our core business and disruption of ongoing operations.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete, and integrate suitable target businesses, technologies, or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations. To finance any acquisitions, investments, or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all.

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

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, CDMOs, and vendors including but not limited to contract research organizations, or CROs. Misconduct by these parties could include intentional, unintentional, reckless, and/or negligent conduct that fails to comply with FDA or other comparable regulations, provide true, complete and accurate information to the FDA and other comparable regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of our product candidate or any future product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

We, our collaborators, and our service providers are subject to a variety of privacy and data security laws, regulations, and contractual obligations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with them could expose us to significant fines and other penalties and otherwise harm our business and operations.

The legislative and regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, numerous jurisdictions, including those in which we operate or collect personal information, have established their own data security and privacy frameworks with which we must comply. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state information security and 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, and protection of health-related and other personal information, could apply to our operations or the operations of our collaborators and service providers. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and impose requirements regarding the privacy and security of individually identifiable health information, including mandatory contractual terms, for covered entities, or certain healthcare providers, health plans and healthcare clearinghouses, and their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. While pharmaceutical and biotechnology companies are typically not directly regulated by HIPAA, our business may be indirectly impacted by HIPAA in our interactions with providers, payors, and others that have HIPAA compliance obligations. If we are unable to properly protect the privacy and security of protected health information, we could be found to have violated these privacy and security laws and/or breached certain contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant civil and criminal penalties. U.S. Department of Health & Human Services, or HHS, enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

At the state level, numerous states have or are in the process of enacting or considering comprehensive data privacy and security laws, rules, and regulations while other states have focused on more narrow aspects of privacy. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In the state of Washington, for example, the My Health My Data Act, which has a private right of action that further increases the relevant compliance risk, requires regulated entities to obtain consent to collect health-related information and grants consumers certain rights, including to request deletion of their information. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states, such as Illinois and Texas, have passed laws that regulate biometric data specifically. Although many of the existing state privacy laws exempt clinical trial information and health information governed as "protected health information" by HIPAA, future privacy and data protection laws may be broader in scope. Taken together, these state and federal laws may be subject to varying interpretations by the courts and government agencies and are subject to frequent change. Further, these varying interpretations could create complex compliance issues for us and our partners and potentially expose us to additional expense, liability, penalties, negatively impact our business, and lead to adverse publicity, and all of these risks could adversely affect our business in the short and long term. In addition, contractual obligations and in the future, legislation may limit, forbid or regulate the use or transmission of health information outside of the United States or across other national borders, which could make reliance on non-U.S. resources for work related to such processing personal information impracticable or substantially more expensive.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets and/or confidential know-how, unpatented know-how, and/or other proprietary information. We may rely on other proprietary rights, including protection of trade secrets, confidential know-how, unpatented know-how, and/or other proprietary information to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To maintain the confidentiality of this type of information, it is our policy to enter into confidentiality agreements with our employees, consultants, advisors, collaborators, contractors (including CDMOs and CROs) and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual(s) or made known to the individual by us during the course of the individual's relationship or work with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the

course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and/or individuals with whom we have these agreements may not comply with their terms, intentionally or unintentionally. Thus, despite such agreements, inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants, contractors, or others use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us or a current or future licensor is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party, or from that individual's assignee. Such assignment or license may not be available at all or on commercially reasonable terms. The disclosure of our trade secrets could impair our competitive position and may materially harm our business, financial condition, and results of operations.

Enforcing a claim that a third party illegally obtained our trade secrets and/or confidential know-how and is using these is expensive, time consuming, and unpredictable. The enforceability of confidentiality agreements and theft of trade secret claims may vary from jurisdiction to jurisdiction. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. As such, adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets afford no protection against such independent discovery. Such persons may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, such persons could limit our use of our trade secrets and/or confidential know-how. Under certain circumstances and to guarantee our freedom to operate, we may also decide to publish some know-how to prevent others from obtaining patent rights covering such know-how.

Risks Related to the Discovery and Development of Our Current or Future Product Candidates

Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval, and if obtained, ultimately commercialize them.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual regulatory approval and commercialization of our current product candidate or future product candidates we develop, which may never occur. Our current product candidate and any future product candidates we develop will require significant preclinical or clinical development, management of clinical, preclinical, and manufacturing activities, efforts toward obtaining marketing approval in the United States and other jurisdictions, and if approved, demonstration of effectiveness to pricing and reimbursement authorities, sufficient manufacturing supply for both preclinical and clinical development and, if approved, for commercial production, as well as investments to build a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales.

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

- timely and successful completion of our preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- our plans to successfully submit amendments to existing INDs or new INDs with the FDA for our current and future product candidates;

- our ability to complete preclinical studies for current or future product candidates;
- successful enrollment of subjects in, and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidate in the intended patient populations;
- our ability to establish and maintain agreements with third-party manufacturers on a timely and cost-efficient manner;
- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our lead product candidate, amsoki-cel;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidate by the FDA and comparable foreign regulatory authorities;
- timely receipt and maintenance of marketing approvals from applicable regulatory authorities;
- successfully launching commercial distribution and sales of our product candidate, if approved;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced with our product candidate, if approved;
- entry into collaborations to further the development of our product candidate;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidate;
- acceptance of the benefits and uses of our product candidate, if approved, by patients, the medical community, and third-party payors;
- maintaining an acceptable safety, tolerability, and efficacy profile of the product candidates following approval;
- our compliance with any post-approval requirements imposed on our products, such as post-marketing studies, a Risk Evaluation and Mitigation Strategy, or REMS, or additional requirements that might limit the promotion, advertising, distribution, or sales of our products or make the products cost prohibitive;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending intellectual property rights and claims.

These factors, many of which are beyond our control, could cause us to fall behind our competitors, experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that any other current or future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize our product candidates or any future product candidates, we must demonstrate through data from extensive preclinical studies and clinical trials that our

product candidate and any future product candidates are safe, pure, and potent in humans. Clinical trials are expensive and can take many years to complete, with a highly uncertain outcome. Failure can occur at any time during the clinical trial process and our current or future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We cannot be certain the ongoing and planned preclinical studies or clinical trials for our current or any other future product candidates will begin on time, not require redesign, enroll an adequate number of eligible subjects on time, or be completed on schedule, if at all. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- results from preclinical studies or clinical trials may not be predictive of results from later clinical trials of any product candidate;
- the FDA or other regulatory authorities, Institutional Review Boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or may produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product candidate development programs;
- the number of patients required for clinical trials may be larger than we anticipate, or we may have difficulty in recruiting and enrolling patients to participate in clinical trials, including as a result of the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications and clinical trial subjects;
- enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or may fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our CROs and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- our product candidates could cause undesirable or harmful side effects that could result in significant negative consequences, including the inability to enter or continue clinical development or to receive regulatory approval;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates;

- the supply, quality, or timeliness of delivery of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- we may need to change the manufacturing site and potentially the CDMO for our product candidates from those that are able to produce clinical supply for our clinical trials to those with the capacity and ability to perform commercial manufacturing and/or the production of clinical material for our later stage clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, or by the IRBs of the institutions in which such trials are being conducted, ethics committees, or the Safety Review Committee, or SRC, or the Data and Safety Monitoring Board, or DSMB, for such trial or by the FDA, the EMA, or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidate.

The FDA, the EMA, or other regulatory authorities may change the expectations for approval even after they have reviewed and commented on the design for our clinical trials. Further, the FDA, the EMA, or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials. For example, we are conducting and may in the future continue to conduct “open-label” clinical trials. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect because patients may be subject to a “patient bias” where they perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical trials often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

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

If we experience delays in enrollment or completion of, or the suspension or termination of, any clinical trial of our lead product candidate, amsoki-cel, including the registration-enabling melanoma cohort of our Agni-01 study, the commercial prospects of amsoki-cel will be harmed and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidate, and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidate.

Any such events would impair our ability to successfully commercialize our product candidate and may harm our business and results of operations. Any of these occurrences may significantly harm our business, financial

condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidate or result in the development of our product candidate stopping early.

Preclinical development is uncertain. Any preclinical programs we pursue may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

The risk of failure for product candidates still in the discovery or preclinical stage is high. In addition, any one or more of our product candidates that have not yet entered the clinic may never advance into clinical development. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity, and potency, including efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical candidates on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA, the EMA, or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming, and expensive process. The length of time of such testing may vary substantially according to the type, complexity, and novelty of the program, and often can be several years or more per program. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to:

- failure of animal studies to generate compelling toxicity data;
- failure of new non-animal methods for preclinical work to be accepted by regulators; and
- delays or failures by third party CROs conducting the nonclinical studies on our behalf.

Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses.

We may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We are currently conducting clinical trials in the United States. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. 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 (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, foreign clinical trials are subject to the applicable local laws of the foreign jurisdictions where such trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result

in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to (i) test safety, (ii) study pharmacokinetics and pharmacodynamics, and (iii) understand the side effects of product candidates at various doses and schedules, and the results of any early-stage clinical trials may not be predictive of the results of later-stage, large-scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development our product candidates. There is a high failure rate for drugs and biological products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our current or future product candidates may demonstrate different chemical, biological, and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show desired pharmacological properties or produce the necessary safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations, and prospects.

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

From time to time, we may publish interim data, including interim, top-line, or preliminary data from our preclinical studies and clinical trials. Any interim data and results from our preclinical studies and clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or topline data and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary or top-line results also remain subject to audit, validation, and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Material differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Furthermore, third parties, including regulatory authorities, 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 delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial

is based on what is typically extensive information, and you or others may not agree with what we determine to disclose. If 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.

Our current or future product candidates may cause undesirable, unacceptable, or serious adverse side effects or have other properties when used alone or in combination with other approved products or investigational new drugs or biological products that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

Before obtaining regulatory approvals for the commercial sale of our product candidate, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that our current and any future product candidates are safe, pure, and potent for use in each target indication, and failures can occur at any stage of testing. As with most biological products, use of our current or future product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. There have been serious adverse side effects reported in response to engineered TIL cell therapies in oncology.

Immuno-oncology drugs have been observed to cause side effects, generally related to over activation of the immune system. These include colitis, diabetes, pituitary inflammation, thyroiditis, myocarditis, liver inflammation, thrombocytopenia, pneumonitis, hypoxia, cytokine release syndrome, late autoimmune side effects/autoimmune disease states, and risk of death, among others. Our immuno-oncology product candidates, and combination drug regimens may have similar or additional side effects including late autoimmune side effects, autoimmune disease states or secondary malignancies. Treatment-related side effects may emerge at a later time in our trials. In addition to any potential side effects caused by the product candidate or combination regimen, the administration process or related procedures also can cause adverse side effects. If unacceptable adverse events occur, our clinical trials could be suspended or terminated, or any future marketing authorization could be suspended, revoked, or varied. Additionally, we may be required to repeat or conduct additional clinical trials or nonclinical studies for our product candidate beyond those that we currently contemplate. There can be no assurance that any of our current or future product candidates will not demonstrate unacceptable toxicities in later testing that may render them unsafe or intolerable.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our trials are conducted, or the DSMB or SRC could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates and train them in the tumor procurement surgical and core needle biopsy processes. There are additional risks of complications from tumor tissue procurement, including surgical complications and core needle biopsy complications, including the risk of death. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Engineered TIL cell therapeutics and their method of action of harnessing the body’s immune system are powerful and could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after a product candidate has been approved by regulatory authorities and the approved product

has been marketed, following the exposure of additional patients. Even though data to date from our Phase 1/2 clinical trial has demonstrated a favorable safety and tolerability profile for amsoki-cel in patients with advanced melanoma, clinical trial results are subject to significant uncertainty, and we cannot assure you that our ongoing or future clinical trials will demonstrate comparable safety, tolerability or efficacy results. If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed.

In addition, we may pursue our product candidate or develop future product candidates in combination with other therapies, which could expose us to additional risks relating to undesirable side effects or other properties. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidate or the combination of our product candidate with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. The other therapies we are using in combination may be removed from the market, or we may not be able to secure adequate quantities of such materials for which we have no guaranteed supply contract, and thus such therapies may be unavailable for testing or commercial use with any of our approved products. The other therapies we may use in combination with our product candidate may also be supplanted in the market by newer, safer, or more efficacious products or combinations of products.

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

Even if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. If our current product candidate or any of our future product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result in the following, including but not limited to:

- regulatory authorities may limit, suspend, or withdraw their approval of the product or may refuse to approve supplemental applications for such product; regulatory authorities may refuse to approve pending applications or supplements to approved applications we file;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues, which would materially harm our

business. In addition, if our product candidates or our engineered TIL cell therapeutic development approach generally proves to be unsafe, our entire technology platform and pipeline could be affected, which would also materially harm our business.

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

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to recruit and enroll a sufficient number of eligible patients who remain in the trial until the trial's conclusion, including any follow-up period. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the nature and size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the number and location of participating and available clinical sites or patients;
- delays in the ability or failure to add new clinical trial sites;
- the design of the trial;
- our ability to recruit qualified clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies;
- our ability to obtain and maintain patient informed consents for participation in our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. It is also likely that we may compete with competitors developing product candidates in the same therapeutic areas for clinical trial sites. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll in our ongoing or any future clinical trial.

Delays or difficulties in patient enrollment may result in increased costs or may affect the timing, outcome, or completion of clinical trials, which would adversely affect our ability to advance the development of the product candidates we develop.

Because the number of subjects included in our clinical trials to date has been small, results from these trials may be less reliable than results achieved in larger clinical trials.

A trial design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary

results of trials with smaller sample sizes and heterogeneous patient populations, can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the trial results less reliable than trials with a larger number of subjects and with more homogeneous patient populations. As a result, there may be less certainty that our product candidates would achieve a statistically significant effect in any future clinical trials. As our clinical development progresses, later-stage or larger clinical trials may not achieve statistically significant results or demonstrate the same safety or efficacy profile observed in our earlier clinical trials.

Risks Related to Our Dependence on and Work with Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, CROs and contract development manufacturing organizations, or CDMOs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our current and future product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, third-party CROs and CDMOs to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the competent authorities of the member states of the European Economic Area, or EEA, and comparable foreign regulatory authorities for our current and future product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the 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 the product candidate produced under the FDA's current good manufacturing practice, or cGMP, regulations or similar foreign regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our current and future product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our current and future product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations, comply with applicable regulatory requirements or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidate and any of our future product candidates. As a result, our results of operations and the commercial prospects for our product candidate or any future product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We may depend on other third-party collaborators for the discovery, development, and commercialization of certain of our current and future product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We have formed, and in the future, we may form or seek strategic alliances, joint ventures, or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. Such potential future collaborations involving our product candidates may pose various risks to us, including:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations and collaborators may not perform their obligations as expected. In some situations, we may not be able to influence our collaborators' decisions regarding the development of our product candidates, and as a result, our collaborators may not pursue or prioritize the development of those product candidates in a manner that is in our best interest or that we agree with;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly obtain, enforce, maintain, or defend our intellectual property rights or proprietary rights or may use our proprietary information in a way that gives rise to actual or threatened litigation or that could jeopardize or invalidate our intellectual property or proprietary information, exposing us to potential litigation or other intellectual property proceedings;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development, or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources. Such disputes may also impact our intellectual property ownership and other rights;
- a collaborator with marketing and distribution rights to our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of the product candidate, potentially leading to regulatory investigations or proceedings that may slow down product development;

- collaborators may delay clinical trials, provide insufficient funding or resources for clinical trials or marketing and distribution of a product, stop a clinical trial, abandon a product candidate or repeat or conduct new clinical trials;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

If we enter into collaboration agreements and strategic partnerships or license our intellectual property, products, or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or net income that justifies the entry into such transaction. Any of the factors set forth above, among others, could delay the development and commercialization of our product candidate, which would harm our business prospects, financial condition, and results of operations.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidate and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our current or future product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations 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 collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA, the EMA, or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The 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. The terms of any collaboration or other arrangements that we may establish may not be favorable to us.

Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Such exclusivity could limit our ability to enter into strategic collaborations with future collaborators. 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.

We may not be able to 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 the product candidate for which we are seeking to collaborate, 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 marketing or sales activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or any future product candidates or bring them to market and generate product revenue.

In addition, any future collaboration that we enter into may not be successful. The success of future collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties can often be terminated by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We are required to pay substantial royalty and milestone payments under our license agreement with M.D. Anderson, and we must also meet certain development milestones to maintain our license rights.

In October 2021, we entered into a license agreement with The Board of Regents, or the Board of Regents, of The University of Texas System, on behalf of M.D. Anderson Cancer Center, or M.D. Anderson, for our engineered TIL cell therapy, or the M.D. Anderson License Agreement. Under the M.D. Anderson License Agreement, we are required to pay both substantial milestone payments and royalties to M.D. Anderson based on the net sales of our products utilizing the licensed technologies. These payments could adversely affect the overall profitability for use of any products that we may seek to commercialize under the M.D. Anderson License Agreement. In order to maintain our license rights under the M.D. Anderson License Agreement, we also need to meet certain specified development milestones, subject to certain cure or extension provisions. There is no assurance that we will continue to be able to meet these development milestones on a timely basis, or at all.

Risks Related to Manufacturing of Our Product Candidates

We currently rely on and expect to continue to rely on a network of third-party suppliers and other third parties for production of our current and future product candidates including TIL products and viral vectors as well as custom critical materials such as anti-41BB and iFeeders, and our dependence on these third parties may impair the advancement of our research and development programs and the development of our current and future product candidates.

We rely on and expect to continue to rely on a network of third-party CDMOs for the supply of cGMP-grade clinical trial materials and commercial quantities of our current and future product candidates as well as custom critical materials. Specifically, we collaborate with a network of leading CDMOs to manufacture amsoki-cel, including membrane-bound IL15 carbonic anhydrase 2, or mbIL15-CA2, DRD, viral vector, anti-41BB and iFeeders. Reliance on a network of third-party providers may expose us to more risk than if we were to manufacture our product candidates and the associated critical materials ourselves. The facilities used by our CDMOs to manufacture our engineered TIL candidates and the associated materials must be approved by the FDA and foreign regulatory authorities pursuant to inspections that will be conducted after we submit our BLA to the FDA, or similar applications to foreign regulatory authorities. We have limited control over the manufacturing process of, and beyond contractual terms, we are largely dependent on our CDMOs for compliance with cGMP, and applicable product tracking and tracing requirements, or similar foreign requirements for the manufacture of our product candidate. If our CDMOs cannot successfully manufacture

material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, or are unable to do so in a timely manner, they may not be able to secure or maintain regulatory approval for their manufacturing facilities and could result in delay of our ability to obtain marketing authorization of our current and future product candidates. In addition, we have limited control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our current and future product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or if approved, market our product candidate. In addition, any failure to achieve and maintain compliance with these laws, regulations, and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidate or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement with us because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. Any such changes could cause our current and future product candidates to perform differently and affect the results of clinical trials conducted with the altered materials, and limit our ability to rely on data from clinical trials conducted with an earlier version of our product candidates. In addition, the fact that we are dependent on our collaborators, our CDMOs, and other third parties for the manufacture, filling, storage, and distribution of our current and future product candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition, and results of operations.

We rely on our CDMOs to purchase from third-party suppliers the materials necessary to produce our current product candidate for our clinical trials, and will rely on our existing and future collaborators to purchase from third-party suppliers the materials necessary to develop and produce our product candidates for future clinical trials and, upon approval, our products for commercialization.

Moreover, if approved, we intend to rely on third parties to produce commercial supplies of our engineered TIL candidates and viral vectors as well as custom critical materials such as anti-41BB and iFeeders. Our commercialization of any of our product candidate could be stopped, delayed, or made less profitable if those third parties fail to obtain approval of the FDA or comparable foreign regulatory authorities following inspection of their facilities and procedures to manufacture our product candidate and products, fail to provide us with sufficient quantities of product or product components and materials, or fail to do so at acceptable timing, quality levels, or prices, or fail to otherwise complete their duties in compliance with their obligations to us or other parties.

We are dependent on a limited number of suppliers and, in some instances, a sole supplier, for some of our components and materials used in our product candidates.

There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidate for our clinical trials, and if approved, ultimately for commercial sale. Apart from contractual measures, we do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers or manufacturers paid by our collaborators. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of our product candidate to complete the clinical trial or have secured resupply capacity, any significant delay in the supply of our product candidate, or the raw material components thereof, for a planned or an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidate.

In addition, the manufacturing of our product candidate is expensive and time-consuming. If we are successful in obtaining regulatory approval for any of our product candidates, we might have limited quantities of such product candidates available to us in connection with a potential commercial launch, and these supplies may be further limited by our ongoing clinical development activities. If our manufacturers, collaborators or we are unable to purchase or produce sufficient quantities of raw materials or of our product candidate after regulatory approval has been obtained for our product candidate, the commercial launch of our product candidate could be delayed or there could be a shortage in supply, which in either case, would impair our ability to generate revenues from the sale of our product candidate.

We rely on our manufacturers and other subcontractors to comply with and respect the proprietary rights of others in conducting their contractual obligations for us. If our manufacturers or other subcontractors fail to acquire the proper licenses or otherwise infringe third-party proprietary rights in the course of completing their contractual obligations to us, we may have to find alternative manufacturers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidate, if approved.

The operations of our suppliers are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

We currently rely on and engage third-party manufacturers to provide critical raw materials, all of the active pharmaceutical ingredients, or APIs, and the final drug product formulation of our product candidate that are being used in our clinical trials and preclinical studies. If a replacement manufacturer became necessary in the future, we may incur added costs and delays in identifying and qualifying another manufacturer. As a result of our global suppliers, we may be subject to risks associated with doing business abroad, including:

- geopolitical tensions, political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, information and data transfer, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate,
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs, and the FDA's current good tissue practices (cGTPs), as applicable, or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional, or local epidemics, pandemics, public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

The National Defense Authorization Act for Fiscal Year 2026 enacted in December 2025 includes a section titled, "Prohibition on Contracting with Certain Biotechnology Providers," also known as the BIOSECURE Act, aimed at discouraging federal contracting with certain biotechnology companies for biotechnology equipment or services in China and other countries of concern. The statute prohibits federal executive agencies from procuring any biotechnology equipment or service from a biotechnology company of concern, or BCC, or contracting with any such company or any entity that procures or uses equipment or services from a BCC. Any company on the Department of Defense's Chinese Military Companies List (1260H list) is considered a BCC under the new law and the White House Office of Management and Budget also is empowered to designate companies as BCCs based on consultations with Cabinet Secretaries and other key leaders from the executive branch. This legislation

may have the effect of restricting the ability of biopharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain and other foreign Chinese biotechnology companies.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our supplier's ability to procure certain materials, any of which could delay our clinical trials or otherwise harm our business, financial condition, results of operations, and prospects.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential 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 processes and results. In addition, we will likely need to change or expand our CDMO network for manufacturing our product candidates to one that can support commercial-scale manufacturing. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification, or FDA approval. 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 candidate, and jeopardize our ability to commence sales, if approved, and generate revenue.

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidate.

The process of manufacturing our engineered TIL product candidates is complex, time-consuming, highly regulated, and subject to several risks, including:

- manufacturing cellular therapies is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product candidate or intermediate would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our product candidates at costs, or in sufficient quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA or comparable regulatory authorities not agree with our product candidate specifications and comparability assessments for these materials, further clinical development of our product candidates could be substantially delayed and we would incur substantial additional expenses.
- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

- we will likely need to expand our CDMO network for manufacturing our product candidate to meet clinical and commercial demand;
- we will need to expand and develop relationships with suppliers of critical starting materials or reagents, increase the scale of production and demonstrate comparability of the material produced at these facilities to the material that was previously produced. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented knowledge that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We would expect additional comparability work will also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know-how and data have been adequately incorporated into the manufacturing process until the completion of studies and the related evaluations intended to demonstrate the comparability. If we are not able to successfully transfer and produce comparable product candidates, our ability to further develop and manufacture our product candidates may be negatively impacted;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures, and numerous other factors;
- differences in tumor procurement across sites may give us a suboptimal starting material;
- it may be difficult to meet comparability standards across multiple CDMOs; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives.

Amsoki-cel comprises a live cell suspension of autologous TIL derived from the patient's tumor that have been engineered to express mbIL15. As an autologous cell therapy, the manufacture of amsoki-cel involves complex processes, including tumor collection, tumor processing, pre-Rapid Expansion Protocol, or Pre-REP, harvest, cryopreservation, storage in liquid nitrogen, or LN2, Pre-REP thaw, activation, transduction, Rapid Expansion Protocol, or REP, harvest, and cryopreservation, LN2 storage, quality testing and release, LN2 shipment, clinical site receipt, thaw and patient administration. Our manufacturing process may be susceptible to product loss or failure due to logistical issues associated with collection of the patients' tumor materials, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the finished cell therapy product. Product loss or failure may also be caused by manufacturing issues associated with the variability in patient starting material, differences in tumor procurement across clinical sites, interruptions in the manufacturing process, contamination, equipment or utility failure, assay failures, improper installation or operation of equipment, vendor or operator error, GMP issues, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions.

We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as improving process performance, introducing new raw materials, decreasing processing time, increasing manufacturing success rate, costs improvement, achieving scale, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidate to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidate, our business will be materially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval, or maintain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, the Oncology Center of Excellence within the FDA has advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, an initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options; and Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research, and innovation in approval and post-marketing processes, with the goal to enhance the balance. We are considering these and other policy changes as they relate to our programs.

We have not obtained regulatory approval for any of our product candidates. Neither we nor any future collaborator is permitted to market any biological product in the United States until we or the future collaborator receives regulatory approval of a BLA, from the FDA. It is possible that none of our current or future product candidates will ever obtain regulatory approval from the FDA or comparable foreign regulatory authorities.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate has an acceptable risk-benefit profile in the proposed indication;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that the facility in which a product candidate is manufactured meets standards designed to assure that the product candidate is safe, pure, and potent;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidate may not be sufficient to support the submission of a BLA to the FDA or regulatory submissions to comparable regulatory authorities to obtain regulatory approval in such jurisdiction; and
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations, and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from ongoing and future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, the FDA may approve any of our product candidates for fewer or more limited indications, or a more limited patient population, than we request, may grant approval contingent on the performance of costly clinical trials or other post-marketing requirements, or may approve a product candidate with a label that does not include the labeling claims we believe are necessary or desirable for the successful commercialization of such product candidates. Even if we obtain regulatory approval for our product candidate, we will be required to submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process and the FDA or comparable foreign regulatory authority may refuse to approve such applications or supplements.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, promulgate additional regulations, revise existing regulations, or take other actions that may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations we may have obtained. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidate.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Without the appropriation of adequate funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted.

Disruptions at the FDA and other agencies, including substantial leadership, personnel, and policy changes, may also slow the time necessary for biological products or modifications to approved biological products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, changes and cuts in FDA staffing during 2025 have been seen as resulting in delays in the FDA's responsiveness or in its ability to review IND submissions or marketing applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion.

With the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to the extent and manner in which the administration will continue to seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutics candidates. Also, state governments may seek to

address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

We may be required to suspend, repeat, or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, or the trials are not well designed.

Clinical trials must be conducted in accordance with GCP requirements, which are regulations and guidelines enforced by the FDA, the competent authorities of the member states of the EEA, and comparable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies, and IRBs or ethical committees at the trial sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP requirements. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or trial protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to trial subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- the product candidate may not appear to offer benefits over current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

Even if we receive marketing approval of our product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non-compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution.

Any marketing approvals that we receive for any current or future product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require implementation of a REMS as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, quality control, labeling, packaging, distribution, tracking and tracing, adverse event and deviation reporting, storage, advertising, promotion, import and export, and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP regulations and with GCP requirements for any clinical trials that we may conduct post-approval. Problems with our or our third-party manufacturers' manufacturing processes or facilities, or failure to comply with regulatory requirements, may result in, among other things:

- suspension of, or imposition of restrictions on, the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- adverse inspectional observations (FDA Form 483s), Warning Letters or Untitled Letters, or full or partial holds on clinical trials;
- suspension of production or distribution;

- product seizure or detention, monetary penalties, refusal to permit the import or export of the product, or placement on Import Alert; and
- permanent injunctions and consent decrees including the imposition of civil or criminal penalties.

Given the nature of biological product manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials and other components required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product or product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development and commercialization timelines and our business, financial condition, results of operations and prospects and could adversely affect our ability to meet our supply obligations.

Moreover, the FDA and the U.S. Department of Justice strictly regulate the promotional claims that may be made about drug and biological products. In particular, an approved product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, or off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. The FDA has issued guidance on the factors that it will consider in determining whether a firm's product communication is consistent with the FDA-required labeling for that product, and those factors contain complexity and potential for overlap and misinterpretation. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal, and administrative penalties.

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

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, the value of our company and our operating results will be adversely affected.

In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

While we intend to seek designations for our potential product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process or an accelerated regulatory pathway, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our potential product candidates are granted such designations, we may not be able to realize the intended benefits of such designations or maintain such designations.

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway, and priority review.

Amsoki-cel (OBX-115) has been granted Fast Track and RMAT designation from the FDA for the treatment of patients with unresectable or metastatic melanoma that is resistant to immune checkpoint inhibitors, or ICI,

therapy. We may seek designations for other indications, or for future product candidates. However, there can be no assurance that we will successfully obtain such designations for any additional indications or future product candidates, or that we will be able to maintain the designations we have been granted. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our potential product candidates, there can be no assurance that we will realize their intended benefits. For example, we may seek fast track designation for additional indications or for our other potential product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and its nonclinical or clinical data demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if Fast Track Designation has been granted, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide assurance of the product's ultimate FDA approval. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

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

In addition, we may seek a RMAT designation for additional indications or for our other potential product candidates. RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our potential product candidates meets the criteria for designation as a regenerative medicine advanced therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our potential product candidates qualify for RMAT designation, the FDA may later decide that the biological products no longer meet the conditions for qualification.

We may also seek rare pediatric disease designation for some of our potential product candidates. Under the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, we will need to request a rare pediatric disease priority review voucher, or PRV, in our original marketing application for any eligible potential product candidates. The FDA may determine that a marketing application for any such product candidate, if approved, does not meet the eligibility criteria for a PRV. Vouchers for rare pediatric disease drugs are awarded for qualifying applications when the drug receives approval. Under current law, after September 30, 2029, the FDA may not award any rare pediatric disease priority review vouchers, although the FDA's authority to do so could be extended by the U.S. Congress in the future.

We are pursuing a development strategy for amsoki-cel in advanced melanoma that is intended to support potential accelerated approval. Although we have received FDA feedback regarding a single-arm trial design for potential accelerated approval, the study is being conducted at our risk, and such feedback does not constitute a commitment by the FDA that the design, endpoints or data generated will be sufficient to support a BLA or accelerated approval. The accelerated approval pathway may be used in cases in which the advantage of a new biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval may be contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the biologic's clinical benefit. In case of an accelerated BLA approval, FDA may mandate a Phase 4

clinical trial prior to full approval. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Moreover, even if we received accelerated approval, any post-approval studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. Receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate's marketing application for priority review. A priority review designation means that the goal for the FDA to review an application is six months from the filing date, rather than the standard review period of ten months. We may request priority review for the product candidates that we develop. The FDA has broad discretion with respect to whether to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

In addition, in the European Union, we may seek to participate in the PRIority Medicines, or PRIME, scheme for our potential product candidates. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure in the European Union. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Eligible products must target conditions for which there is an unmet medical need (no treatment option exists in the European Union or, they can offer a major therapeutic advantage over existing treatments). Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. There is no guarantee, however, that our potential product candidates would be deemed eligible for the PRIME scheme and even if we do participate in the PRIME scheme, where during the course of development a product no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

We may seek a Commissioner's National Priority Voucher for one or more of our current and planned product candidates. We may not receive such a voucher, and even if we do, may not be able to fully realize the benefits of such a voucher, including a decision within 1-2 months following filing of a complete application for the relevant drug or biologic candidate.

In June 2025, the FDA announced the creation of a new program, the Commissioner's National Priority Voucher, or CNPV, pilot program, to expedite the development and approval of drug products with potential to address a major national priority, such as addressing a large unmet medical need, reducing downstream health care utilization, addressing a public health crisis, boosting domestic manufacturing, or increasing medication

affordability. The FDA has stated that voucher recipients will receive a decision on an accelerated basis as well as enhanced communication with review staff throughout the development process prior to final submission of the application and during the review period. For additional information regarding the CNPV pilot program, see the section titled "*Business—Government Regulation—Licensure and Regulation of Biologics in the United States—Expedited Programs*."

However, receipt of the CNPV does not guarantee that the BLA will be approved on an expedited basis or at all. The FDA has stated that the review time for an application of a CNPV recipient may be extended, including because the application is incomplete, there are manufacturing violations, if the results of pivotal trial(s) are ambiguous, if the review is particularly complex, or for other reasons deemed appropriate by the FDA. The CNPV program is in a pilot stage, so its implementation, operation, and ultimate benefits or impacts are subject to uncertainty.

Risks Related to Commercialization

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

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

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

If our product candidate or any future product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, or patients, we may not generate sufficient revenue from

that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved. The number of patients who have the types of cancer or autoimmune diseases we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. The number of patients who receive second- and third-line treatment is significantly smaller than the number of patients who receive first-line treatment, and the prognosis of patients who receive second- or third-line treatment is often poorer than that of patients who receive first-line treatment.

We may initially seek approval for any other product candidates we develop as second- or third-line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

If approved, our product candidate that is regulated as a biological product, or biologic, may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, established an abbreviated pathway for the approval of biosimilar and interchangeable biologics with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product or sponsor's data and is not submitted as a biosimilar application. Certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. The law is complex and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the

subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, biosimilars compete with, and in some circumstances may be deemed under state law to be substitutable for, the previously approved reference product. The approval of a biosimilar of our product candidate could have a material adverse impact on our business due to increased competition and pricing pressure. It is also possible that payors will give reimbursement preference to biosimilars over reference biological products, even absent a determination of interchangeability.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference biological product. Any market entry of competing products to our product candidate in these other regions could adversely affect our business in those regions.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our current product candidate or any future product candidates it could adversely affect our business, financial condition, results of operations and prospects.

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

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

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States, Canada or overseas. Any failure or delay in the development of our internal or a third parties' sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

Off-label use or misuse of our product candidate may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If amsoki-cel or any future product candidates are approved by the FDA, we may only promote or market such product candidates in a manner consistent with their FDA-approved labeling. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our product candidates off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the

use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

If we or any third-party manufacturer we engage now or in the future fails to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. 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. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance as well as 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.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health, and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm, or experience a disruption in the manufacture and supply of our product candidate or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health, and safety laws and regulations.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends, in part, on obtaining and maintaining patents and other forms of intellectual property rights for our technology, including product candidates (including clinical product candidates and preclinical product candidates), methods used to produce, purify, and manufacture those product candidates, and methods of utilizing the product candidates, including methods for treating patients, among other aspects of our technology or on licensing-in such rights. Failure to protect or to obtain, maintain, or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our product candidates or future product candidates.

Our strategy depends in part on our ability to identify and seek patent protection for our discoveries. The patent prosecution process is time-consuming and expensive, and we and our current or future licensors, licensees, or collaborators may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a

reasonable cost or in a timely manner in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our current or future licensors, licensees, or collaborators will fail to identify patentable aspects of inventions made in the course of development activities before it is too late to obtain patent protection on them.

The standards which the United States Patent and Trademark Office, or the USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change in the future. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, the issuance, scope, validity, enforceability, and commercial value of our and our current or future licensors', licensees', or collaborators' current and future patent rights are highly uncertain. We cannot predict whether additional patents protecting our technology will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide a competitive advantage. Our current or future licensors', licensees', or collaborators' pending and future patent applications may not result in patents being issued which protect our product candidates or other technology, in whole or in part, or which effectively prevent others from commercializing competitive products and technology. The patent examination process may require us or our current or future licensors, licensees, or collaborators to narrow the scope of the claims of our or our current or future licensors', licensees', or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained.

We cannot confirm that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, or have issued and even if such patents cover a product candidate, and/or other technologies, third parties may initiate an adversarial proceeding including opposition, interference, re-examination, post-grant review, inter partes review, litigation, nullification, or derivation action before patent offices or in court, or similar proceedings challenging the validity, enforceability, or scope, inventorship, or ownership of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable or unavailable to us.

Patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of the first priority application, or in some cases not at all, and publications of discoveries in scientific literature lag behind actual discoveries. As such, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any notice or compensation to us or may limit the scope of patent protection that we or our licensors are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

Finally, our current and future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the claimed technology in such applications unless and until a patent issues from

such application(s), and then only to the extent the issued claims cover the technology in the relevant jurisdiction, and, if applicable, until the patent survives an opposition, interference, re-examination, inter partes review, and the like with claims that continue to cover the technology.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting, and defending patents on our product candidate or any future product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained 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. As such, we will not file for patent protection in all national and regional jurisdictions in the world where such protection may be available.

Accordingly, competitors may use our and our existing or future licensors', licensees', or collaborators' 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 existing or future licensors, licensees, or collaborators have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidate or other technologies, and our and our existing or future licensors', licensees', or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, and the requirements for patentability differ, in varying degrees, from country to country, and the laws of some foreign countries do not protect intellectual property rights, including trade secrets, to the same extent as federal and state laws of the United States. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. Such issues may make it difficult for us to stop the infringement, misappropriation, or other violation of our intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Furthermore, proceedings to enforce our patent rights and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuit that we initiate, and the damages or other remedies awarded to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties

may be significant. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Issued patents covering our product candidates and related technology could be found invalid or unenforceable if challenged in court or before a patent office.

Issued patents may be challenged, narrowed, invalidated, or circumvented. We may from time to time need to resort to litigation (or other adversarial proceedings) to enforce or defend any patents or other intellectual property right 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. As enforcement of intellectual property rights is difficult, unpredictable, and expensive, we may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being enjoined, required to pay us any license fees, or compensate us for lost profits or reasonable royalty. In addition, 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 technology covered by our patents we seek to enforce, such as those covering our product candidates and related methods, among other technologies, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates or other technologies, the defendant could counterclaim that our patent is invalid and/or unenforceable, which is commonplace in patent litigation in the United States and in other foreign jurisdictions. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements for patentability, for example, lack of utility, novelty, obviousness, non-enablement, or lack of written description or as constituting unpatentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone substantively involved in prosecution of the patent withheld but-for material information from the USPTO or engaged in affirmatively egregious misconduct, during prosecution, with a specific intent to deceive the USPTO.

The outcome following legal assertions of invalidity and unenforceability during patent litigation (or other adversarial proceedings) is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our product candidate or other technology. Such a loss of patent protection could have a material adverse impact on our business. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. 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.

If we are unsuccessful in defending against claims by competitors or others that we are infringing upon their intellectual property rights, our business could be materially harmed.

Our commercial success will depend, in part, on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or other proprietary rights that could limit our ability to make, use, sell, offer for sale, or import a product candidate, a future approved product, or impair our competitive position. There may be issued patents and/or pending patent applications held by third parties that could be alleged as covering our product candidate, irrespective of the merits. Although we believe that these patents are not infringed, and/or are invalid and/or unenforceable, if a court should find that they cover our product candidates and we are unable to invalidate such patents, or if licenses for them are not available or on commercially reasonable terms, our business could be harmed, perhaps materially.

We believe that if such patents or patent applications were asserted against us, we would have counterclaims and defenses against such claims, including non-infringement, the affirmative defense of safe harbor designed to

protect activity undertaken to obtain federal regulatory approval of a cell therapy, including under 35 U.S.C. § 271(e) and similar foreign exceptions to infringement, and defenses concerning patent invalidity and/or unenforceability. However, if such counterclaims and defenses are not successful and such patents are successfully asserted against us such that they are found to be valid and enforceable, and infringed, unless we obtain a license to such patents, which may not be available or on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize our product candidate. We could also be required to pay substantial damages. We cannot confirm that we will ultimately prevail if any such third-party intellectual property is asserted against us.

In the biotechnology industry, significant litigation and other proceedings regarding patents, patent applications, trademarks, and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

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

These lawsuits (or other adversarial proceedings) would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

In addition, if the breadth or strength of protection provided by our present or future licensors', collaborators', or partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates. 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.

Third-party intellectual property right holders, including our competitors, may actively bring infringement claims against us. We may not be able to successfully settle, license (including on commercially acceptable terms), or otherwise resolve such potential infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable, and time-consuming litigation and may be prevented from or experience substantial delays in marketing any approved products. If we fail in any such dispute, in addition to being forced to potentially pay damages, we or our collaborators may be temporarily or permanently prohibited from commercializing our product candidates that are held to be infringing or be forced to redesign product candidates so that we no longer infringe the third-party's intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, research, and development.

The biotechnology industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patented claims of the relevant patent or that the patented claims are invalid, and we may not be able to do this. Proving invalidity can be difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action, or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully, or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidate to market, and be precluded from manufacturing or selling our product candidates.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

It is also possible that in our evaluation of third-party intellectual property, we failed to identify relevant patents or applications. We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patented claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidate in any jurisdiction.

The scope of a patented claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidate. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until the patent issues. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to claim broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidate or related technology. We cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims.

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

We may become a party to litigation and other adversarial proceedings or disputes involving intellectual property in the US and in other jurisdictions. Such litigation (or other adversarial proceedings or disputes) include instances where we are asserting our intellectual property against third parties, or we are defending against an

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

If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are currently party to intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various obligations on us. For example, we have entered into patent and know-how license agreements with the Board of Regents of The University of Texas System that grant us the right to use certain technologies related to our clinical product candidates and related methods. If we fail to comply with our obligations under the licenses, the licensor may have the right to terminate their respective license agreements, in which event we might not be able to market any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business.

We have rights in some intellectual property that have been discovered through United States government funded programs and thus are subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry.

We have rights in some intellectual property that was developed through U.S. government funded programs and thus are subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. For example, some of the intellectual property rights licensed to us under our M.D. Anderson License Agreement were generated using U.S. government funds. As a result, the U.S. government has certain rights to intellectual property embodied in certain current or future products pursuant to the Bayh-Dole Act of 1980. These U.S. government rights in certain inventions developed under government-funded programs include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as march-in rights. The U.S. government also has the right to take title to these inventions if the applicable licensor fails to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under U.S. government-funded programs is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. This requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible. This

preference for U.S. manufacturing may limit our ability to license the applicable patent rights on an exclusive basis under certain circumstances.

We may be unsuccessful in licensing or acquiring third-party intellectual property that may be required to develop and commercialize our product candidate.

We have rights, through patents that we have in-licensed or own, to the intellectual property to develop our product candidates. Because our programs may involve additional product candidates that may require the use of intellectual property or proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use such intellectual property and proprietary rights of others. We may be unable to acquire or in-license any third-party intellectual property or proprietary rights or to do so on commercially reasonable terms. For example, we sometimes collaborate with public or private academic institutions to accelerate our research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the strategic collaboration. Regardless of such option, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us, and the institution may license such intellectual property rights to third parties, potentially blocking our ability to pursue our development and commercialization plans. The same situation may occur with a present or future development partner.

The licensing and acquisition of third-party intellectual property and proprietary rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property and proprietary rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size and greater capital resources and development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property and proprietary rights to us.

If we are unable to successfully acquire or in-license rights to required third-party intellectual property and proprietary rights or maintain our intellectual property and proprietary rights, we may have to cease development of the relevant program, product, or product candidate, which could have a material adverse effect on our business.

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.

The USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent prosecution and post grant or issuance. We employ reputable law firms and other professionals to help us comply. Additionally, periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and/or patent applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We rely on our outside counsel or our agents to pay these fees when due. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a 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 such an event were to occur, it could have a material adverse effect on our business.

In addition, we may be responsible for the payment of patent fees for patent rights that we license from third parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights. If we or our existing

or future licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

Patents typically have a limited lifespan. In the United States and in most ex-U.S. jurisdictions, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date, not including potential patent term extensions or adjustments that may be available in the United States, and under comparable laws applicable outside the United States, where certain conditions are met. 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 candidate, we may be open to competition from competitive cell therapies. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, causing our revenue from applicable products to be reduced, possibly materially, and potentially harming our ability to recover our investment in such product or obtain a reasonable return on that investment.

Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates or any future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or are concurrently employed at other biotechnology or pharmaceutical companies, universities, and/or research institutions and the like, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former or concurrent employers, or that patents and applications we have filed to protect inventions of these employees, even those related to our product candidate, are rightfully owned by their former or concurrent employer.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. 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 or on commercially reasonable terms or at all.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish our product candidates that are approved for marketing from the products of our competitors. However, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversions of resources and could adversely affect our business, financial condition, and growth prospects.

In addition, any proprietary name we propose to use with any product candidates in the United States must be approved by the FDA, regardless of whether we have registered it or applied to register it as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify an alternate proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA.

Risks Related to Healthcare, Insurance and Legal Matters

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidate.

We face an inherent risk of product liability exposure related to the testing of our product candidate in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers, or others using, administering, or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate we may develop;
- withdrawal of trial participants;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any product candidates that we may develop.

While we currently hold product liability insurance coverage for clinical trials consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidate, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

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

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidate or any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. For more information, see the section of this prospectus titled "*Business—Government Regulation—Coverage, Pricing and Reimbursement*" beginning on page 128 of this prospectus.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions, and fines should we be found to be in violation of any applicable obligations thereunder.

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

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidate or any future product candidates.

Obtaining and maintaining reimbursement status is time-consuming, costly, and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and

reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely. For products administered under the supervision of a physician (including products administered in the clinical setting), obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the administration of the product, or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

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

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare and Medicaid beneficiaries, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. In addition, the U.S. Supreme Court's June 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays and/or changes. If we are slow or unable to adapt to changes to existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidate may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We are subject to various U.S. federal, state, and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable

foreign, federal, and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, and plan to market, sell, and distribute any products for which we obtain regulatory approval. In particular, the research of our product candidates, as well as the promotion, sales and marketing of our product candidates is subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. For more information about the applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate, see the section of this prospectus titled "*Business—Government Regulation—Other U.S. Healthcare Laws and Compliance Requirements*" beginning on page 126 of this prospectus.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize our product candidate or any future product candidates and may adversely affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell our product candidate or any future product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the Inflation Reduction Act of 2022, or the IRA, includes several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, among others. Our lead product candidate, amsoki-cel, is being developed in indications that may rely on Medicare reimbursement. Accordingly, these price-negotiation provisions may have a negative impact on our future revenue and profits. Further, the IRA also imposed rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation.

The One Big Beautiful Bill Act of 2025, or the OBBBA, also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our revenue and commercial prospects.

For more information, see the section of this prospectus titled "*Business—Government Regulation—Healthcare Reform*" beginning on page 129 of this prospectus.

Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidate and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations, and prospects.

We expect that these existing laws and other federal and state healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our potential products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidate or any future product candidates, if approved.

Failure to comply with laws and regulations related to the protection of research subjects could result in fines, penalties, and litigation, and have a material adverse effect upon our business.

We may be subject to regulation under international, federal, state, and local laws and regulations relating to the protection of research subjects. Federally funded human-subject research in the United States, including the collection of identifiable human biospecimens, is governed by 45 CFR Part 46, also known as the Health and Human Services Policy for Protection of Human Research Subjects or the "Common Rule." Use of biospecimens in certain other research is subject to FDA regulations for the Protection of Human Subjects and Institutional Review Boards at 21 CFR Parts 50 and 56. While we believe that we are in compliance with these laws, we may not be aware of all such laws or may fail to properly audit and identify gaps in compliance. Similarly, we may find errors in our product candidate and processes and may fail to properly match the compliance requirements of our researchers to the compliance requirements of our suppliers. Failure of our company or our suppliers to comply with international, federal, state, and local laws and regulations could subject us to denial of the right to conduct business, fines, criminal penalties, and/or other enforcement actions which could have a material adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

Our ability to develop product candidates and our future growth depends on attracting, hiring, and retaining our key personnel and recruiting additional qualified personnel. If we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Additionally, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. The loss of services of any of these individuals could delay

or prevent the successful development of our product candidate, completion of our planned clinical trials, or the commercialization of our product candidate and any future product candidates.

Our success also depends upon the continued contributions of our key management and scientific personnel, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates, and building the technologies related to the clinical development of our product candidate. Historically, we have experienced significant turnover in our research and development workforce and have operated with a limited team of scientific and technical personnel. Given the specialized nature of engineered TIL technology and our approach, there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidate in our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key personnel, in particular our scientists, would delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology and biopharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical, and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

As our development plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, marketing, sales, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- managing our internal development efforts effectively, including the clinical and FDA review process for our current product candidates and any future product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial, and management controls, reporting systems, and procedures.

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part, on certain independent organizations, advisors, and consultants to provide certain services. We cannot assure you that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current product candidates and any future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

Other General Risks

Unfavorable global economic and geopolitical conditions could adversely affect our business, financial condition, stock price, and results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes in U.S. federal policy that affect the geopolitical landscape. Changes to policy implemented by the U.S. Congress, the current administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. For example, in 2025, the United States imposed tariffs on imports on its trading partners, including Canada, Mexico, the EU and China. Historically, tariffs have led to increased trade and political tensions, between not only the United States and China, but also between the United States and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

The global credit and financial markets have also experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation, and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflicts between Russia and Ukraine, the conflicts in the Middle East, terrorism, or other geopolitical events. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. For example, there has been proposed U.S. legislation that may restrict the ability of U.S. biopharmaceutical companies to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We continue to assess the legislation as it develops to determine whether it could have an effect on our contractual relationships. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

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

Natural disasters or public health crises could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition, and prospects. If a natural disaster, power outage, public health crisis, or other event occurred that prevented us from conducting our clinical trials, releasing clinical trial results, or delaying our ability to obtain regulatory approval for our product candidate, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer cybersecurity incidents or breaches, which could adversely affect our business.

Despite the implementation of security measures, our information technology systems and data and those of our current or future CROs or other contractors and consultants are vulnerable to compromise or damage from computer hacking, computer viruses, social engineering (e.g. phishing attacks) and malware (e.g., ransomware malicious software), fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are constantly increasing in frequency and sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, "hacktivists," nation states, and others. As a result of a continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Further, as a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of the attacks described herein, there is a risk that an attack may remain undetected for a period of time. Even if identified, we may be unable to adequately investigate or remediate cybersecurity incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we continue to make investments to improve the protection of data and information technology, including in the hiring of IT personnel, periodic cyber security awareness trainings, and improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or cybersecurity incidents or breaches.

We and certain of our service providers are from time to time subject to cyberattack attempts or incidents and cybersecurity incidents. Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any significant cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to cybersecurity incident or breach notification requirements, regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties, result in substantial costs, and require attention from management. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price and stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing, or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

For example, the loss of clinical trial data from completed, ongoing, or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a cybersecurity breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release, or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidate and other third parties for the manufacture of our product candidate and to

conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our collaborators, or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or cybersecurity incident or breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidate could be delayed, result in substantial costs and require attention from management.

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

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have implemented the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires annual management assessment of the effectiveness of our internal control over financial reporting beginning with our Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2026. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years following the closing of the Mergers. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

As a result of the completion of the Mergers and PIPE Financing, we are now subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to

make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

As of December 31, 2025, we had approximately $186.5 million of federal net operating losses, or NOLs. Federal NOLs generated in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of our taxable income. As of December 31, 2025, we had approximately $171.0 million of state NOLs. Of the state NOLs, some are of indefinite life, but most are of definite life with various expiration dates, beginning in 2037. As of December 31, 2025, we had approximately $17.1 million of federal research and development tax credit carryforwards. Federal tax credit carryforwards expire at various dates, beginning in 2037. As of December 31, 2025, we had approximately $7.7 million of state research and development tax credit carryforwards. The state tax credits, which have various carryforward rules, begin to expire in 2031. Our ability to utilize these NOLs and tax credits to offset future tax liabilities depends on the successful development of our product candidates and future financial performance.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by "5 percent shareholders" over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). We may have experienced ownership changes in the past, including as a result of the Mergers and the PIPE Financing, and may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which are outside our control). There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to NOLs and research and development tax credits, could adversely affect us or holders of our common stock. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the United States may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the United States in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the United States in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the

two-taxable year period beginning with the first taxable year beginning after December 31, 2024. In recent years, many changes to tax laws have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on our business and operations.

We may be exposed to increased litigation from stockholders, suppliers and other third parties from time to time, including litigation due to the Mergers. Such litigation may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' common stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Certain stockholders, formerly Galera stockholders, may not receive any payment on the CVRs, and the CVRs may expire valueless.

The right of Galera stockholders to receive any future payment on or derive any value from the CVRs will be contingent solely upon the occurrence of certain milestone events within the time periods specified in the CVR Agreement and the consideration received being greater than the amounts permitted to be withheld or deducted under the CVR Agreement. Specifically, payments under the CVRs with respect to the Legacy Product Agreement are contingent upon CVR Proceeds being received by Parent or its affiliates under any Legacy Product Agreement prior to the fifth anniversary of the closing, and payments under the CVRs with respect to the Supportive-Care Agreement are contingent upon CVR Proceeds being received by Parent or its affiliates under the Supportive-Care Agreement prior to the tenth anniversary of the closing. There is no guarantee that Parent will receive any proceeds under either CVR Product Agreement within the applicable time periods. In the event that no CVR Proceeds are received within the applicable time periods, no payments will be made under the CVR Agreement, and the CVRs will expire valueless.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled "*Prospectus Summary*," "*Risk Factors*," "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," and "*Business,*" contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the initiation timing, progress, results and cost of amsoki-cel, as well as our research and development programs and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our current and future programs;
- the ability to identify research priorities and efficiently discover and develop product candidates, including by applying learnings from one program to other programs and from one modality to our other modalities;
- the ability and the potential to successfully manufacture our drug substances, delivery vehicles, and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- the ability of our preclinical studies and clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our product candidates;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of Investigational New Drug applications and final U.S. Food and Drug Administration, or FDA, approval of our current product candidates or any future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our estimates of the number of patients that we will enroll and our ability to initiate, recruit and enroll patients in and conduct and successfully complete our clinical trials at the pace that we project;
- our ability to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs, which will require significant resources;
- our ability to maintain and further develop the specific shipping, storage, handling and administration of amsoki-cel at the clinical sites;
- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, and strategic plans for our business, product candidates, and technology;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- estimates of our future expenses, revenues and capital requirements and our needs for additional financing;
- future agreements with third parties in connection with the development and commercialization of product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing costs;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- the period over which we estimate our cash, cash equivalents, and marketable securities will be sufficient to fund our future operating expenses and capital expenditure requirements;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those listed under the caption "*Risk Factors*."

In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "*Risk Factors*" and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

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 prospectus, 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.

USE OF PROCEEDS

The selling stockholders will make offers and sales pursuant to this prospectus. We will not receive any of the proceeds of such offerings. The selling stockholders will pay any underwriting discounts and commissions and expenses they incur for brokerage, accounting, tax or legal services, or any other expenses they incur in disposing of their shares. We will incur certain expenses in connection with the registration with the SEC of the shares of our common stock to be sold by the selling stockholders.

MARKET PRICE OF AND DIVIDEND ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information and Holders

Our common stock is listed on Nasdaq under the symbol "OBX." Our common stock commenced trading on the Nasdaq on August 4, 2026.

As of August 24, 2026, there were approximately 208 holders of record of our common stock. The number of holders of record does not include a substantially greater number of "street name" holders or beneficial holders whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

SELECTED UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL DATA OF OBSIDIAN

Defined terms included below and not otherwise defined shall have the same meaning as terms defined and included elsewhere in this prospectus.

Introduction

As previously announced, on April 14, 2026, Gazelle Parent, Inc. (now known as Obsidian Therapeutics, Inc.), or the Parent, entered into the Merger Agreement with Legacy Galera, Legacy Obsidian, Obsidian Merger Sub and Galera Merger Sub, pursuant to which (1) Obsidian Merger Sub merged with and into Legacy Obsidian, with Legacy Obsidian surviving as a wholly owned subsidiary of Obsidian Therapeutics, Inc., and (2) immediately thereafter, Galera Merger Sub merged with and into Legacy Galera, with Legacy Galera surviving as a wholly owned subsidiary of Obsidian Therapeutics, Inc. References to "Parent" herein refer to Gazelle Parent, Inc., which was renamed Obsidian Therapeutics, Inc., following the closing of the Mergers.

Also on April 14, 2026, Legacy Galera entered into the Securities Purchase Agreement with certain investors, pursuant to which Legacy Galera sold, and such investors purchased, shares of Legacy Galera's Series C preferred stock for an aggregate purchase price of approximately $350.0 million (less any proceeds received by Legacy Obsidian in connection with a Permitted Obsidian Bridge Financing (as defined in the Securities Purchase Agreement)), or the PIPE Financing. The PIPE Financing closed on July 31, 2026.

On August 3, 2026, the Mergers were completed pursuant to which (a) Obsidian Merger Sub merged with and into Legacy Obsidian, pursuant to the provisions of the General Corporation Law of the State of Delaware, as amended, or the DGCL, with Legacy Obsidian as the surviving entity, or the Obsidian Merger, and (b) immediately following the Obsidian Merger, Galera Merger Sub merged with and into Legacy Galera, pursuant to the DGCL, with Legacy Galera as the surviving entity, or the Galera Merger, and together with the Obsidian Merger, the Mergers.

The merger agreement provided that, (1) prior to the effective time of the Galera Merger, all of the outstanding shares of Legacy Galera preferred stock, as well as the Legacy Galera pre-funded warrants, would be converted into Legacy Galera common stock and (2) prior to the effective time of the Obsidian Merger, all of the outstanding shares of Legacy Obsidian preferred stock, as well as the Banc of California, Inc. warrants of Legacy Obsidian would be converted into Legacy Obsidian common stock.

At the Obsidian Merger effective time, each outstanding share of Legacy Obsidian common stock (including those resulting from the conversion of the Legacy Obsidian preferred stock, the Legacy Obsidian Banc of California, Inc. warrants, and Legacy Obsidian common stock issued in connection with any interim permitted financings, but excluding dissenting shares and certain excluded shares as described in this prospectus) was converted into the right to receive a number of shares of Parent Common Stock calculated as described in the information statement/prospectus filed by Parent on July 2, 2026.

Immediately following the effective time of the Obsidian Merger, at the Galera Merger effective time, each outstanding share of Legacy Galera common stock (including those resulting from the conversion of the Legacy Galera preferred stock and the Legacy Galera pre-funded warrants, but excluding dissenting shares and certain excluded shares as described in this prospectus) was converted into the right to receive a number of shares of Parent Common Stock calculated as described in the information statement/prospectus filed by Parent on July 2, 2026.

Legacy Galera Reverse Stock Split

On July 12, 2026, Legacy Galera effected a one-for-two hundred (1:200) reverse stock split, or the Galera Reverse Stock Split, of Legacy Galera's common stock, which has been retroactively applied to the unaudited pro forma condensed combined financial statements for all periods presented.

While Parent is the legal acquirer, Legacy Obsidian is deemed to be the accounting acquirer of Legacy Galera. The acquisition of Legacy Galera is accounted for as an asset acquisition as Legacy Galera does not meet the definition of a business as defined within Accounting Standards Codification Topic 805, Business Combinations, or ASC 805, as Legacy Galera only has inputs and no substantive processes or outputs at the time of acquisition. The Legacy Galera assets acquired are measured based on the estimated fair value of the consideration paid, inclusive of direct transaction costs. The Legacy Galera In-Process Research and Development, or IPR&D, acquired was determined to have no alternative future use to the continuing company and was immediately expensed. The unaudited pro forma condensed combined financial information set forth below primarily gives effect to the following:

- closing of the PIPE Financing immediately prior to the closing of the Mergers;
- closing of the Obsidian Merger;
- closing of the Galera Merger;
- the conversion of Legacy Galera common stock and Legacy Galera preferred stock into Parent Common Stock;
- the conversion of Legacy Obsidian common stock and Legacy Obsidian preferred stock into Parent Common Stock; and
- the application of asset acquisition accounting in connection with the Mergers.

At the effective time of the Mergers, Parent issued (or reserved for issuance upon exercise of options assumed in the Mergers) an aggregate of approximately (i) 31,831,595 shares of Parent Common Stock to Legacy Obsidian securityholders, (ii) 777,236 shares of Parent Common Stock to Legacy Galera securityholders, and (iii) 29,164,045 shares of Parent Common Stock to investors in the PIPE Financing, resulting in approximately 61,772,876 shares of common stock being issued and outstanding immediately following the effective time of the Mergers. Immediately following the effective time of the Mergers, the (i) Legacy Obsidian securityholders owned approximately 51.5% of the outstanding shares of Parent Common Stock, (ii) Legacy Galera securityholders owned approximately 1.3% of the outstanding shares of Parent Common Stock and (iii) investors in the PIPE Financing owned approximately 47.2% of Parent Common Stock.

The unaudited pro forma condensed combined balance sheet assumes that the Mergers and PIPE Financing took place on June 30, 2026, and combines the historical balance sheets of Legacy Galera and Legacy Obsidian as of such date. The unaudited pro forma condensed combined statements of operations for the six months ended June 30, 2026 and the year ended December 31, 2025 assume that the Mergers took place as of January 1, 2025, and combines the historical results of Legacy Galera and Legacy Obsidian for the six months ended June 30, 2026 and the year ended December 31, 2025. The unaudited pro forma condensed combined financial information was prepared pursuant to the rules and regulations of Article 11 of SEC Regulation S-X.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Legacy Galera and Legacy Obsidian, and their respective management's discussion and analysis of financial condition and results of operations, included elsewhere in this prospectus.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. The pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed including but not limited to changes in Legacy Galera's assets and liabilities, additional direct and incremental offering costs. Adjustments have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, which has not yet been completed, may occur, and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information is not necessarily indicative of the financial position or results of operations in the future periods or the result that actually would have been realized had Legacy Galera and Legacy Obsidian been a combined organization during the specified period. The actual results reported in periods following the Mergers may differ significantly from those reflected in the unaudited condensed combined pro forma financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET
As of June 30, 2026
(in thousands, except per share data)

See accompanying notes to the unaudited pro forma condensed combined financial statements.

	Obsidian Therapeutics, Inc. (historical)	Galera Therapeutics, Inc.	Transaction Adjustments	Notes	Pro Forma Combined
ASSETS					
Current assets:					
Cash and cash equivalents	$ 17,983	$ 3,458	$ 331,372	A	$ 338,632
			(1,668)	B	
			(12,513)	C	
Marketable securities	16,462	—	—		16,462
Prepaid expenses and other current assets	11,914	465	(6,827)	D	5,552
Total current assets	46,359	3,923	310,364		360,646
Property and equipment, net	1,201	—	—		1,201
Right-of-use assets	2,878	—	—		2,878
Restricted cash and other assets	1,004	101	0		1,105
Total assets	$ 51,442	$ 4,024	$ 310,364		$ 365,830
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)					
Current liabilities:					
Accounts payable	$ 365	$ 2,149	$ (1,834)	E	$ 680
Accrued expenses and other current liabilities	17,853	1,027	(7,654)	F	11,226
Operating lease liabilities, current portion	1,974	—	—		1,974
Financing lease liabilities	4	—	—		4
Total current liabilities	20,196	3,176	(9,488)		13,884
Operating lease liabilities, net of current portion	928	—	—		928
Other non-current liabilities	1	—	(1)	G	—
Total liabilities	21,125	3,176	(9,489)		14,812
Redeemable convertible preferred stock	330,028	—	(330,028)	H	—
Stockholders' equity (deficit):					
Common stock	2	1	(1)	I	62
			29	H	
			1	J	
			1	K	
			29	A	
Additional paid-in capital	41,722	314,013	(313,165)	I	718,198
			329,999	H	
			1	G	
			(1)	J	
			21,113	K	
			331,343	A	
			(6,827)	D	
Accumulated other comprehensive income	(3)	—	—		(3)
Accumulated deficit	(341,432)	(313,166)	313,166	I	(367,239)
			(1,668)	B	
			(3,025)	C	
			(21,114)	K	
Total stockholders' equity (deficit)	(299,711)	848	649,881		351,018
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 51,442	$ 4,024	$ 310,364		$ 365,830

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS
For the Six Months ended June 30, 2026

(in thousands, except per share data)

	Obsidian Therapeutics, Inc.	Galera Therapeutics, Inc.	Transaction Adjustments	Notes	Pro Forma Combined
Operating expenses:					
Research and development	$ 37,281	$ 40	$ —		$ 37,321
General and administrative	9,139	5,900	—	AA	15,039
Total operating expenses	46,420	5,940	—		52,360
Loss from operations	(46,420)	(5,940)	—		(52,360)
Interest and other income	923	88	—		1,011
Net loss	$ (45,497)	$ (5,852)	$ —		$ (51,349)
Net loss attributable to common stockholders, basic and diluted	$ (45,497)	(3,910)	$ (1,942)	BB	$ (51,349)
Net loss per share of common, basic and diluted	$ (2.30)	$ (5.37)			$ (0.84)
Weighted-average shares of common stock outstanding, basic and diluted	19,751,933	727,681	40,956,303	CC	61,435,917
Net loss attributable to Series B redeemable convertible preferred stockholders, basic and diluted		$ (1,942)	$ 1,942	DD	$ —
Net loss per share of Series B redeemable convertible preferred stock, basic and diluted		$ (16.30)	$ 16.30	DD	$ —
Weighted-average shares of Series B redeemable convertible preferred stock outstanding, basic and diluted		119,122	(119,122)	DD	—

See accompanying notes to the unaudited pro forma condensed combined financial statements.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
For the Year Ended December 31, 2025

(in thousands, except share and per share data)

	Obsidian Therapeutics, Inc.	Galera Therapeutics, Inc.	Transaction Adjustments	Notes	Pro Forma Combined
Operating expenses:					
Research and development	$ 86,113	$ 349	$ —		$ 86,462
General and administrative	19,554	5,693	(69)	AA	25,178
Gain on sale of dismutase mimetics assets	—	(3,500)			(3,500)
Total operating expenses	105,667	2,542	(69)		108,140
Loss from operations	(105,667)	(2,542)	69		(108,140)
Other income (expense):					
Interest and other income	5,060	248	—		5,308
Gain on extinguishment of debt	—	151,049	—		151,049
Change in fair value of warrant liability	—	294	—		294
Total other income	5,060	151,591	—		156,651
Net loss	$ (100,607)	$ 149,049	$ 69		$ 48,511
Net income (loss) attributable to common stockholders, basic and diluted	$ (100,607)	$ 63,524	$ 76,948	BB	$ 39,865
Net income (loss) per share of common, basic and diluted	$ (7.22)	$ 128.98			$ 0.65
Weighted-average shares of common stock outstanding, basic and diluted	13,935,769	492,517	47,180,062	CC	61,608,348
Net income attributable to Series B redeemable convertible preferred stockholders, basic and diluted		$ 76,948	$ (76,948)	DD	$ —
Net income per share of Series B redeemable convertible preferred stock, basic and diluted		$ 644.89	$ (644.89)	DD	$ —
Weighted-average shares of Series B redeemable convertible preferred stock outstanding, basic and diluted		119,318	(119,318)	DD	—

See accompanying notes to the unaudited pro forma condensed combined financial statements.

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

Note 1—Description of the Transactions

On April 14, 2026, Legacy Galera, Legacy Obsidian, Obsidian Merger Sub, Galera Merger Sub, and Parent entered into the merger agreement, pursuant to which (i) Obsidian Merger Sub merged with and into Legacy Obsidian, with Legacy Obsidian surviving as a wholly-owned subsidiary of Parent and (ii) immediately thereafter, Galera Merger Sub merged with and into Legacy Galera, with Legacy Galera surviving as a wholly owned subsidiary of Parent. Legacy Obsidian and Legacy Galera have historical operating businesses, and Parent was incorporated to serve as the parent company for the combined businesses following the closing of the Mergers.

While Parent is the legal acquirer, Legacy Obsidian is deemed to be the accounting acquirer of Legacy Galera. The acquisition of Legacy Galera is accounted for as an asset acquisition as Legacy Galera does not meet the definition of business as defined within Accounting Standard Codification Topic 805, Business Combinations, or ASC 805, as Legacy Galera had inputs and no substantive processes or outputs at the time of acquisition. The Legacy Galera assets acquired are measured based on the estimated fair value of the consideration paid, inclusive of direct transactions costs. The Legacy Galera IPR&D acquired was determined to have no alternative future use and was immediately expensed.

Galera Reverse Stock Split

On July 12, 2026, Legacy Galera effected a one-for-two hundred (1:200) reverse stock split, or the Galera Reverse Stock Split, of Legacy Galera's common stock, which has been retroactively applied to the unaudited pro forma condensed combined financial statements for all periods presented.

PIPE Financing

Concurrent with the execution and delivery of the Merger Agreement, Legacy Galera and certain investors executed the Securities Purchase Agreement, pursuant to which such investors agreed to purchase shares of Legacy Galera Series C preferred stock immediately prior to the closing of the Mergers, for aggregate gross cash proceeds of $350.0 million (less any proceeds received by Legacy Obsidian in connection with a Permitted Legacy Obsidian Bridge Financing (as defined in the Securities Purchase Agreement)) before commissions and estimated expenses. The PIPE Financing was completed on July 31, 2026.

Employment Arrangements

The employment agreements for Legacy Galera employees included entitlement to change in control payments for certain executives and severance for certain non-executives, that were treated as pre-merger compensation expense of Legacy Galera and reflected as a reduction in cash of Legacy Galera. To the extent such severance costs and any other termination costs were not settled in cash by Legacy Galera prior to closing, they were assumed by the combined company at closing and adjusted through Legacy Galera's valuation.

CVRs

Immediately prior to completing the Mergers, Parent and Legacy Obsidian entered into the CVR Agreement with Equiniti Trust Company, LLC as rights agent, pursuant to which Legacy Galera stockholders of record as of the close of business on the last business day prior to the effective time of the Galera Merger (but, for clarity, after the conversion of all Legacy Galera Series B preferred stock into Legacy Galera common stock and before the issuance of any Legacy Galera Series C preferred stock) received CVRs representing the right to receive contingent cash payments upon the occurrence of certain events. There are two types of CVRs: (i) one CVR with respect to the Legacy Product Agreement (as defined in the CVR Agreement) and (ii) one CVR with respect to the Supportive-Care Product Agreement (as defined in the CVR Agreement), for each such share of Legacy Galera common stock. The CVRs with respect to the Legacy Product Agreement relate to tilarginine, Legacy Galera's legacy product candidate, and entitle holders to receive a pro rata portion of 80% of the net proceeds

received by Parent or its affiliates under any Legacy Product Agreement during the applicable CVR period, with such period expiring on the fifth anniversary of the closing of the Mergers. The CVRs with respect to the Supportive-Care Product Agreement relate to GC4419, GC4711 and related compounds, and entitle holders to receive a pro rata portion of 95% of the CVR Proceeds (as defined in the CVR Agreement) received by Parent or its affiliates under the Supportive-Care Product Agreement during the applicable CVR period, with such period expiring on the tenth anniversary of the closing of the Mergers. In each case, each holder will be entitled to receive its pro rata portion of the applicable percentage of CVR Proceeds, calculated by multiplying such percentage by a fraction equal to the total number of CVRs of the applicable type held by such holder divided by the total number of CVRs of the applicable type held by all holders, less applicable tax withholding.

Legacy Obsidian concluded that the CVRs represent contingent consideration in connection with an asset acquisition. Due to the contingent nature and uncertainties associated with future payments to holders of the CVRs, Parent will account for CVRs when such future payments become probable and are payable to the CVR holders. The unaudited pro forma condensed combined financial statements assume CVR payments were not probable and not payable following the closing of the Mergers to which no pro forma adjustments have been presented.

Gain on Extinguishment

In October 2025, Legacy Galera entered into an asset purchase agreement with Biossil pursuant to which Legacy Galera sold its dismutase mimetics assets and assigned its royalty purchase agreement with Blackstone Life Sciences, or Blackstone, to Biossil. In connection with this transaction, Biossil assumed all rights and obligations under the royalty purchase agreement, and Blackstone executed a notice of assignment releasing Legacy Galera from further obligations. As a result, Legacy Galera extinguished the royalty purchase liability of approximately $151.0 million and recorded a gain on extinguishment of debt during the year ended December 31, 2025. The unaudited pro forma condensed combined financial statements do not include any adjustments to reflect this non-recurring gain which is not anticipated to provide a benefit to the continuing company.

Note 2—Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X and depicts the Legacy Galera Reverse Stock Split and accounting for the Mergers and the PIPE Financing. The unaudited pro forma condensed combined balance sheet as of June 30, 2026 assumes that the Legacy Galera Reverse Stock Split, Mergers and the PIPE Financing had been approved or consummated on June 30, 2026 and combines the historical June 30, 2026 balance sheets of Legacy Galera and Legacy Obsidian. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2026 and the year ended December 31, 2025 assumes that the Legacy Galera Reverse Stock Split, the Mergers and the PIPE Financing took place as of January 1, 2025, and combines the historical results of Legacy Galera and Legacy Obsidian for the six months ended June 30, 2026 and the year ended December 31, 2025, respectively.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. The pro forma adjustments are subject to further revision as additional information becomes available and additional analyses are performed, including but not limited to changes in Legacy Galera's assets and liabilities, additional financing, additional direct and incremental offering costs and the Legacy Galera Reverse Stock Split. Adjustments have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. There may be differences between the pro forma adjustments and the final accounting for the Mergers, which has not yet been completed, and such differences could be material.

The acquisition of Legacy Galera was accounted for as an asset acquisition as Legacy Galera did not meet the definition of business because Legacy Obsidian only acquired inputs from Legacy Galera and no substantive processes or outputs at the time of acquisition. The Legacy Galera assets acquired were measured based on the

estimated fair value of the consideration paid, inclusive of direct transactions costs. The Legacy Galera IPR&D had no alternative future use to the continuing company and was immediately expensed upon completion of the Mergers.

Legacy Obsidian was determined to be the accounting acquirer in the Mergers primarily based on the following considerations:

- Legacy Obsidian stockholders owned a majority of the voting rights of the combined company.
- Legacy Obsidian designated all initial members of the board of directors of the combined company.
- Legacy Obsidian's executive management team became the executive management team of the combined company.
- Following the closing of the Mergers, Parent was renamed Obsidian Therapeutics, Inc. and its headquarters are Legacy Obsidian's current headquarters, in Cambridge, Massachusetts.

As the Mergers were accounted for as an asset acquisition, Legacy Obsidian's assets and liabilities were carried into the books of Parent at their pre-combination carrying amounts. Legacy Obsidian's historical equity carrying values became the equity of the combined company, with the number of shares outstanding and the common stock aggregate par value. For periods prior to the closing of the Mergers, the historical financial statements of Legacy Obsidian became the historical financial statements of the combined company.

The assets and liabilities of Legacy Galera were adjusted upon completion of the Mergers to their fair values, which approximate their carrying values. No goodwill was recognized.

Note 3—Estimated Consideration and Preliminary Purchase Price Allocation

The preliminary fair value of the consideration totaled approximately $22.0 million, inclusive of the estimated Legacy Obsidian transaction costs to be incurred after June 30, 2026 in connection with the asset acquisition, and is summarized as follows (in thousands):

Parent Common Stock issued to Legacy Galera stockholders	14,760
Legacy Galera warrants allocated to consideration paid	3
Legacy Obsidian transaction costs	7,199
Total consideration	21,962

For pro forma purposes, the preliminary fair value of the consideration transferred was calculated based on the closing stock price of Parent Common Stock on August 3, 2026 of $18.99 per share.

Allocation of the preliminary consideration transferred to the net assets acquired and based upon the net assets of Legacy Galera as of June 30, 2026, was as follows (in thousands):

Assets acquired:	
Cash and cash equivalents	$3,458
Prepaid expenses and other assets	566
Total assets acquired	$4,024

Liabilities assumed:		
Accounts payable	$	2,149
Accrued expenses		1,027
Total liabilities assumed		3,176
Net assets acquired	$	848
In process research and development	$	21,114
Total consideration paid	$	21,962

The above allocation of the purchase price is based upon certain preliminary valuations and other analyses that have not been completed as of the date of this filing. Any changes in the estimated fair values of the net assets recorded for this asset acquisition upon the finalization of more detailed analyses of the facts and circumstances that existed at the date of the Mergers will change the allocation of the purchase price. As such, the purchase price allocations for the acquisition are preliminary estimates, which are subject to change. In addition, it was determined that the estimated fair value of any acquired rights from Legacy Galera to future regulatory or sales milestones payments were immaterial at the time of acquisition due to the significant uncertainty in achieving the regulatory milestones and the subsequent commercial success required to achieve the commercial milestones.

Note 4—Pro Forma Adjustments

The unaudited pro forma condensed combined financial information has been prepared to illustrate the effect of the Mergers based on preliminary estimates that could change materially as additional information is obtained. Adjustments to the historical consolidated financial statements of Legacy Galera to conform to the accounting policies of Legacy Obsidian are not expected to be significant.

Pro Forma Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet

The adjustments included in the unaudited pro forma condensed combined balance sheet as of June 30, 2026, were as follows:

(A) To reflect the net proceeds from the Pipe Financing less transaction costs paid at the time of closing of the Mergers.

(B) To reflect Legacy Galera severance payments at the time of closing of the Mergers.

(C) To reflect the payment of transaction costs for Legacy Obsidian and Legacy Galera of $8.3 million and $4.2 million, respectively, at the time of closing of the Mergers.

(D) To reflect the reclassification of Legacy Obsidian deferred costs to additional paid-in capital at the time of closing of the Mergers.

(E) To reflect the payment of transaction costs within accounts payable at June 30, 2026 for Legacy Galera of $1.8 million at the time of closing of the Mergers.

(F) To reflect the payment of transaction costs within accrued expenses at June 30, 2026 for Legacy Obsidian and Legacy Galera of $6.8 million and $0.8 million, respectively, at the time of closing of the Mergers.

(G) To reflect the reclassification of Legacy Obsidian’s liability classified warrants to equity upon conversion into Parent Common Stock at the time of closing of the Mergers.

(H) To reflect the conversion of Legacy Obsidian’s preferred stock into shares of Parent Common Stock at the time of closing of the Mergers.

(I) To reflect (i) the elimination of Legacy Galera’s historical equity balances at June 30, 2026 and (ii) an increase to additional paid-in capital of $0.8 million to reflect the net assets acquired from Legacy Galera at the time of closing of the Mergers.

(J) To reflect the adjustment of Legacy Obsidian's par value to Parent's stated par value at time of closing of the Mergers.

(K) To reflect the equity issued by Parent to Legacy Galera stockholders in connection with the Mergers, inclusive of the immediate expense recognition of the acquired Legacy Galera IPR&D asset, which had no alternative future use at the time of closing of the Mergers.

Pro Forma Adjustments to Unaudited Pro Forma Condensed Combined Statement of Operations

The adjustments included in the unaudited pro forma condensed combined statement for the six months ended June 30, 2026 and the year ended December 31, 2025, were as follows:

(AA) To reflect the elimination of the non-recurring Legacy Obsidian transaction costs incurred during the year ended December 31, 2025 in connection with the Mergers at the time of closing.

(BB) To eliminate the allocation of net income attributable to Legacy Galera Series B redeemable convertible preferred stock upon conversion into common stock at the time of closing of the Mergers.

(CC) The pro forma basic and diluted net loss per common share have been adjusted to reflect the pro forma net loss for the six months ended June 30, 2026 and the year ended December 31, 2025. In addition, the number of shares used to calculate the pro forma basic and diluted net loss per common share has been adjusted to reflect the estimated total number of shares of Parent Common Stock that would be outstanding as of the date of the closing, as if they have been outstanding for the entirety of the period presented. For the six months ended June 30, 2026 and the year ended December 31, 2025, the pro forma weighted average common shares outstanding and pro forma net loss per common share, basic and diluted, were based on the following adjustments:

	Six Months Ended June 30, 2026	Year Ended December 31, 2025
Elimination of Legacy Galera historical weighted average shares outstanding	(727,681)	(492,517)
Adjustment to Legacy Obsidian weighted average shares outstanding for Legacy Obsidian exchange ratio	(17,020,241)	(12,008,451)
Parent Common Stock issued to Legacy Galera securityholders	777,236	777,236
Conversion of Legacy Obsidian preferred stock into Parent Common Stock	28,762,944	29,739,749
Parent Common Stock issued in connection with the PIPE Financing	29,164,045	29,164,045
Pro forma adjustment	40,956,303	47,180,062

(DD) To eliminate the historical net loss per share attributable to the Legacy Galera Series B redeemable convertible preferred stockholders upon conversion of all outstanding Legacy Galera Series B redeemable convertible preferred stock at the time of the closing of the Mergers.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless the context otherwise requires, references in this section to "we," "us," "our" and the "Company" refer to (i) Legacy Obsidian prior to the closing of the Mergers and (ii) Obsidian Therapeutics, Inc. and its consolidated subsidiaries following the closing of the Mergers. References to "Parent" refer to Gazelle Parent, Inc., which was renamed Obsidian Therapeutics, Inc. following the closing of the Mergers. Capitalized terms used but not otherwise defined in this section have the meanings ascribed to them elsewhere in this prospectus.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements for the years ended December 31, 2025 and 2024, unaudited condensed consolidated financial statements as of June 30, 2026 and 2025 and for the three and six months ended June 30, 2026 and 2025, and the related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor infiltrating lymphocytes, or TIL, cell therapies for the treatment of patients with solid tumors. Our proprietary cytoDRiVE™ platform is highly versatile and allows us to leverage drug responsive domains to control protein function, with our initial focus on TIL cell therapies developed from this platform, or cytoTILs™. Our lead product candidate, amsoki-cel, is a novel, genetically engineered, autologous TIL cell therapy currently in a Phase 2 clinical trial for the treatment of advanced melanoma and a Phase 1 clinical trial for the treatment of non-small cell lung cancer, or NSCLC. Our proprietary cytoDRiVE platform has enabled amsoki-cel to have the potential to drive superior tumor-killing activity with a significantly more tolerable safety profile. In contrast to other TIL approaches, amsoki-cel is designed with regulatable membrane-bound IL15, or mbIL15, which drives TIL persistence, eliminates the need to dose toxic interleukin-2 and enables outpatient administration of low-dose lymphodepletion. Furthermore, amsoki-cel can be manufactured using tumor tissue procurement from an outpatient, minimally invasive core needle biopsy. Across a cohort of fifteen patients with treatment-resistant or refractory melanoma in our Phase 1/2 clinical trial, amsoki-cel administration at the recommended Phase 2 dose demonstrated a 67% confirmed objective response rate, or ORR, and significant tumor burden reduction, including two confirmed complete responses. This response rate, to our knowledge, is the highest current ORR shown in this setting across modalities. We believe that, if approved, the more favorable product profile will support rapid market adoption of amsoki-cel relative to currently available TIL cell therapies. Amsoki-cel has been granted Fast Track and Regenerative Medicine Advanced Therapy designations from the U.S. Food and Drug Administration, or the FDA, for the treatment of patients with unresectable or metastatic melanoma that is resistant to immune checkpoint inhibitor, or ICI, therapy. In our Phase 1 clinical trial in NSCLC, early clinical results show robust tumor shrinkage and include multiple confirmed partial responses, or PRs. We expect to present updated melanoma RP2D data in the fourth quarter of 2026, followed by additional NSCLC Phase 1 clinical data in the first half of 2027 and topline data from our melanoma registration-enabling cohort by year-end 2027. We believe our product candidates are distinct from current cell therapies and have the potential to significantly impact the treatment of solid tumors and clinical outcomes of patients with cancer.

To date, we have not generated any revenue from product sales. Our historical revenue has been derived solely from certain collaboration and license agreements, all of which have since expired or concluded. As a result, we

currently do not have any active revenue-generating arrangements, and we do not expect revenue in the near term unless and until we enter into new collaboration agreements or successfully commercialize one of our product candidates.

Since inception, we have incurred significant operating losses and negative cash flows from operations, reflecting our primary focus on advancing our research and development programs, building our platform, and supporting early-stage clinical and preclinical activities. We expect operating losses and negative cash flows to continue for the foreseeable future as we further develop our product candidates, expand our organization, and incur additional costs associated with operating as a public company. Our net losses were $25.9 million and $26.9 million for three months ended June 30, 2026 and 2025, respectively, and $45.5 million and $51.9 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $341.4 million.

We expect our expenses and operating losses will increase substantially as we:

- conduct our ongoing preclinical studies and ongoing and planned clinical trials of amsoki-cel;
- utilize third parties to manufacture amsoki-cel and any future product candidates and related raw materials or, should we decide to do so, build and maintain a commercial-scale current Good Manufacturing Practices, or cGMP, manufacturing facility;
- continue our early research and development activities;
- seek to identify additional research programs and program candidates to expand our pipeline;
- hire additional research and development, clinical, commercial, and operational personnel;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- seek regulatory approvals for amsoki-cel and any of our future product candidates for which we successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any therapies for which we may obtain marketing approval; and
- incur additional costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with an exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums and investor relations costs.

In addition, we have clinical development, regulatory, and commercial milestone payment obligations under our licensing arrangement with the University of Texas M.D. Anderson Cancer Center, or M.D. Anderson, as described below. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies and our ongoing and planned clinical trials and our expenditures on other research and development activities.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for amsoki-cel or any future product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for any of amsoki-cel or future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate significant revenue from sales of amsoki-cel or any future product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements.

On April 14, 2026, Legacy Obsidian entered into the Merger Agreement with Legacy Galera and the other parties thereto, pursuant to which Legacy Obsidian and Legacy Galera would become wholly owned subsidiaries of

Parent upon completion of the Mergers. On July 31, 2026, the PIPE Financing closed and generated gross proceeds of approximately $350.0 million. On August 3, 2026, the Mergers were completed, and Legacy Obsidian and Legacy Galera became wholly owned subsidiaries of Parent.

The proceeds from the PIPE Financing significantly enhanced our liquidity position and are expected to fund our planned operations for at least the next twelve months from the issuance date of our unaudited condensed consolidated financial statements as of and for the six months ended June 30, 2026. Because the PIPE Financing was completed prior to the issuance of such financial statements, management considered the financing in its evaluation of our ability to continue as a going concern.

Based on the completion of the PIPE Financing, management concluded that the conditions and events that previously raised substantial doubt about our ability to continue as a going concern were alleviated as of the issuance date of our unaudited condensed consolidated financial statements as of and for the six months ended June 30, 2026. See "*—Liquidity and Capital Resources*."

As of June 30, 2026, we had cash and cash equivalents and marketable securities of $34.4 million. Based upon our current operating plans, we believe that the net proceeds from the PIPE Financing, together with our existing cash and cash equivalents and short-term investments in marketable securities, will be sufficient to fund our operations into the second half of 2028.

Components of Results of Operations

Revenue

To date, we have not recognized any revenues from product sales. We do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for amsoki-cel or any future product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation charges for those individuals in research and development functions, other internal and external costs associated with our research and development activities, our discovery and research efforts, and the preclinical and clinical development of amsoki-cel and any future product candidates. Our research and development expenses include:

- personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements;
- external expenses, including expenses incurred under arrangements with third parties, such as sponsored research agreements, contract research organizations, contract development and manufacturing organizations, consultants and our scientific advisors;
- the cost of developing and validating our manufacturing process for use in our preclinical studies and ongoing and future clinical trials;
- the cost to obtain licenses to intellectual property and related future payments should certain development and regulatory milestones be achieved;
- costs for laboratory supplies, research materials and reagents; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses.

We expense all research and development costs in the periods in which they are incurred. 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. Such amounts are recognized as expenses as the goods are delivered or the related services are performed, or until it is no longer expected that such goods will be delivered, or such services will be rendered. Most of our research and development expenses have been related to identifying and developing our product candidates. We have not reported program costs because we have not historically tracked or recorded our research and development expenses on a program-by-program basis. In the future, external research and development costs for any individual product candidate will be tracked commencing upon product candidate nomination. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our technology platform and, as such, are not separately classified.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue to conduct our ongoing research and development activities, advance our preclinical research programs toward clinical development, and conduct our current and planned clinical trials.

The timelines and costs of research and development activities are uncertain and can vary significantly for amsoki-cel and any future product candidates or development programs due to the inherently unpredictable nature of preclinical and clinical development. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to preclinical and clinical results, regulatory developments, and ongoing assessments as to each program's commercial potential.

Our future development costs may vary significantly based on various factors such as timely and successful completion of preclinical studies and ongoing and future clinical trials, positive results from our current and future clinical trials, receipt of marketing approvals from applicable regulatory authorities, establishment and maintenance of arrangements with third parties, intellectual property updates, the amount and timing of any milestone payment due under any existing or future license or collaboration agreement or asset acquisition, and continued acceptable safety, tolerability and efficacy profile of amsoki-cel and any future product candidates that we may develop following approval.

A change in the outcome of any of these variables with respect to the development of amsoki-cel or any future product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, the EMA, or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate would be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation charges for those individuals in executive, legal, finance, human resources, facility operations, and other administrative functions. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for auditing, accounting, tax and consulting services, office and information technology costs, insurance costs, and facilities, depreciation and other general and administrative expenses, which include direct or allocated expenses for rent and maintenance of facilities and utilities.

We anticipate that our general and administrative expenses will increase in the foreseeable future to support our increased research and development activities. These increases will likely include increased costs related to the hiring of additional personnel and fees paid to outside consultants, among other expenses. We also anticipate

increased expenses related to audit, accounting, legal, regulatory, and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Other Income, net

Other income, net consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Income Tax Benefit (Expense)

We have historically not incurred significant income taxes. We continue to maintain a full valuation allowance against all of our deferred tax assets based on management's evaluation of all available evidence, including our history of incurring significant losses from operations. As a result, we do not expect to incur material income taxes for the foreseeable future.

Results of Operations

Comparison of the three months ended June 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended June 30, 2026 and 2025 (in thousands):

	Three Months Ended June 30,		Change
	2026	2025	$
Operating expenses:			
Research and development	$21,549	$22,952	$(1,403)
General and administrative	4,591	5,307	(716)
Total operating expenses	26,140	28,259	(2,119)
Other income, net	276	1,363	(1,087)
Income tax benefit (expense)	—	—	—
Net loss	$(25,864)	(26,896)	$ 1,032

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented (in thousands):

	Three Months Ended June 30,		Change
	2026	2025	$
Clinical and manufacturing activities	$12,637	$12,428	$ 209
Compensation and related expenses (including stock-based compensation)	6,174	8,235	(2,061)
Drug discovery and platform	51	417	(366)
Occupancy and all other costs	2,687	1,872	815
Total research and development expenses	$21,549	$22,952	$(1,403)

Research and development expenses were $21.5 million for the three months ended June 30, 2026, compared to $23.0 million for the three months ended June 30, 2025. The decrease of $1.4 million was primarily due to lower personnel-related expenses resulting from organizational actions taken to streamline operations and align our cost structure with current business needs.

General and Administrative Expenses

General and administrative expenses were $4.6 million for the three months ended June 30, 2026, compared to $5.3 million for the three months ended June 30, 2025. The decrease of $0.7 million was primarily due to a decrease in compensation and related activities. These decreases were primarily related to organizational actions taken to streamline operations and align our cost structure with current business needs.

Other Income, net

Other income, net was $0.3 million for the three months ended June 30, 2026, compared to $1.4 million for the three months ended June 30, 2025. The decrease of $1.1 million was due to decreased interest income based on a lower marketable securities balance in 2026 compared to 2025.

Comparison of the six months ended June 30, 2026 and 2025

The following table summarizes our results of operations for the six months ended June 30, 2026 and 2025 (in thousands):

	Six Months Ended June 30,		Change
	2026	2025	$
Operating expenses:			
Research and development	$37,281	$44,078	$(6,797)
General and administrative	9,139	10,784	(1,645)
Total operating expenses	46,420	54,862	(8,442)
Other income, net	923	2,980	(2,057)
Income tax benefit (expense)	—	—	—
Net loss	$(45,497)	(51,882)	$ 6,385

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented (in thousands):

	Six Months Ended June 30,		Change
	2026	2025	$
Clinical and manufacturing activities	$20,448	$24,447	$(3,999)
Compensation and related expenses (including stock-based compensation)	12,102	15,149	(3,047)
Drug discovery and platform	249	567	(318)
Occupancy and all other costs	4,482	3,915	567
Total research and development expenses	$37,281	$44,078	$(6,797)

Research and development expenses were $37.3 million for the six months ended June 30, 2026, compared to $44.1 million for the six months ended June 30, 2025. The decrease of $6.8 million was primarily due to changes in the timing and level of activities supporting our research and development programs. The decrease was partially offset by higher clinical trial expenses associated with the advancement of our clinical studies, including increased patient enrollment, site activities, and other trial-related costs.

General and Administrative Expenses

General and administrative expenses were $9.1 million for the six months ended June 30, 2026, compared to $10.8 million for the six months ended June 30, 2025. The decrease of $1.6 million was primarily due to a decrease in compensation and related activities primarily related to organizational actions taken to streamline operations and align our cost structure with current business needs.

Other Income, net

Other income, net was $0.9 million for the six months ended June 30, 2026, compared to $3.0 million for the six months ended June 30, 2025. The decrease of $2.1 million was due to decreased interest income based on a lower marketable securities balance in 2026 compared to 2025.

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		Change
	2025	2024	$
Operating expenses:			
Research and development	$ 86,113	$ 73,187	$ 12,926
General and administrative	19,554	18,068	1,486
Total operating expenses	105,667	91,255	14,412
Other income, net	5,060	8,146	(3,086)
Income tax benefit (expense)	—	—	—
Net loss	$(100,607)	$(83,109)	$(17,498)

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented (in thousands):

	Year Ended December 31,		Change
	2025	2024	$
Unallocated research and development expenses:			
Clinical and manufacturing activities	$ 52,065	$ 36,831	$15,234
Compensation and related expenses (including stock-based compensation)	25,561	27,475	(1,914)
Drug discovery and platform	1,026	844	182
Occupancy and all other costs	7,461	8,037	(576)
Total research and development expenses	$ 86,113	$ 73,187	$12,926

Research and development expenses were $86.1 million for the year ended December 31, 2025, compared to $73.2 million for the year ended December 31, 2024. The increase of $12.9 million was primarily due to a $15.2 million increase in clinical and manufacturing activities as well as a $0.2 million increase in drug discovery and platform related to the multi-center Phase 1/2 Agni-01 clinical trial. These increases were partially offset by a decrease in costs related to compensation and related expenses (including stock-based compensation), and occupancy and all other costs of $1.9 million and $0.6 million, respectively. These decreases were primarily related to organizational actions taken to streamline operations and align the Company's cost structure with current business needs.

General and Administrative Expenses

General and administrative expenses were $19.6 million for the year ended December 31, 2025, compared to $18.1 million for the year ended December 31, 2024. The increase of $1.5 million was primarily due to an increase in compensation and related activities and an increase in consulting and professional services costs related to additional investments made to support our growth and prepare to operate as a public company.

Other Income, net

Other income, net was $5.1 million for the year ended December 31, 2025, compared to $8.1 million for the year ended December 31, 2024. The decrease of $3.0 million was due to decreased interest income based on a lower marketable securities balance in 2025 compared to 2024.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. Our historical revenue has been derived solely from certain collaboration and license agreements, all of which have since expired or concluded. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our pipeline.

Through June 30, 2026, we had received aggregate gross proceeds of $336.5 million from the issuance of convertible preferred stock, Simple Agreements for Future Equity, and convertible notes in private placements, and $122.5 million in upfront and milestone payments under prior collaboration agreements.

On July 31, 2026, in connection with the Mergers, we completed the PIPE Financing and received gross proceeds of approximately $350 million. The proceeds from the PIPE Financing, together with our existing cash, cash equivalents and marketable securities, constitute our primary sources of liquidity.

Future Funding Requirements

As of June 30, 2026, we had cash equivalents and short-term investments in marketable securities of $34.4 million. Based upon our current operating plans, and the proceeds received from the PIPE Financing completed in connection with the Mergers, together with our existing cash equivalents and marketable securities, we believe we have sufficient capital to fund our operations into the second half of 2028. Our forecast regarding the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain. We may need to raise substantial additional capital in the future.

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

- the type, number, scope, progress, expansions, results, costs, and timing of discovery, preclinical studies and clinical trials of amsoki-cel and any future product candidates;
- the costs and timing of manufacturing for amsoki-cel and any future product candidates and commercial manufacturing;
- the costs, timing, and outcome of regulatory review of amsoki-cel and any future product candidates;
- the terms and timing of establishing and maintaining licenses and other similar arrangements;
- our ability to establish and maintain additional collaborations, partnerships or licenses on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any future collaboration agreements, if any;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, research and development, clinical or other costs under future collaboration agreements, if any;

- the legal costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company;
- the costs associated with hiring additional personnel and consultants as our preclinical and potential future clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if amsoki-cel and any future product candidate are approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products; and
- costs associated with any products or technologies that we may in-license or acquire.

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

Cash Flows

Comparison of the Six Months Ended June 30, 2026 and 2025

The following table sets forth a summary of the net cash flow activity for the six months ended June 30, 2026 and 2025 (in thousands):

	Six Months Ended June 30,	
	2026	2025
Net cash used in operating activities	$(47,284)	$(45,864)
Net cash provided by investing activities	24,019	30,751
Net cash provided by financing activities	843	18
Net decrease in cash and cash equivalents and restricted cash	$(22,422)	$(15,095)

Operating Activities

For the six months ended June 30, 2026, net cash used in operating activities of $47.3 million was comprised of the net loss of $45.5 million and $3.2 million of non-cash items and a $5.0 million change in operating assets and liabilities.

For the six months ended June 30, 2025, net cash used in operating activities of $45.9 million was comprised of the net loss of $51.9 million, $3.9 million of non-cash items and $2.1 million change in operating assets and liabilities.

Investing Activities

For the six months ended June 30, 2026, net cash provided by investing activities of $24.0 million was primarily comprised of the maturities of marketable securities.

For the six months ended June 30, 2025, net cash provided by investing activities of $30.8 million was primarily comprised of $67.0 million of maturities of marketable securities, partially offset by $36.2 million of marketable securities purchases.

Financing Activities

For the six months ended June 30, 2026 and 2025, the cash provided by financing activities did not have a meaningful impact on our operations.

Comparison of the Years Ended December 31, 2025 and 2024

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (90,393)	$ (75,002)
Net cash provided by (used in) investing activities	81,017	(53,874)
Net cash provided by financing activities	20	162,515
Net decrease in cash and cash equivalents and restricted cash	$ (9,356)	$ (33,639)

Operating Activities

For the year ended December 31, 2025, net cash used in operating activities of $90.4 million was comprised of the net loss of $100.6 million, $7.7 million increase of non-cash items and $2.6 million increase of changes in operating assets and liabilities. For the year ended December 31, 2024, net cash used in operating activities of $75.0 million was comprised of the net loss of $83.1 million, $6.4 million increase of non-cash items and $1.8 million increase of changes in operating assets and liabilities.

Investing Activities

For the year ended December 31, 2025, net cash provided by investing activities of $81.0 million was primarily comprised of $162.0 million from the maturities of marketable securities offset by $80.9 million of purchases of marketable securities. For the year ended December 31, 2024, net cash used in investing activities of $53.9 million was primarily comprised of $131.1 million of purchases of marketable securities, partially offset by $78.0 million from the maturities of marketable securities.

Financing Activities

For the year ended December 31, 2025, the cash provided by financing activities did not have a meaningful impact on our operations. For the year ended December 31, 2024, net cash provided by financing activities of $162.5 million was primarily comprised of $160.5 million of proceeds from the Series C financing.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with third parties for preclinical research studies, upcoming clinical trials and testing and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of the service providers, up to the date of cancellation and in the case of certain arrangements may include noncancelable fees.

There were no changes to our leases and license and collaboration agreements during the six months ended June 30, 2026.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements have been prepared in accordance with US generally accepted accounting principles, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates. Our critical accounting policies are those policies that require the most significant judgments and estimates in the preparation of the condensed consolidated financial statements. Management has determined that our most critical accounting policies are those relating to research and development expenses and accruals and stock based compensation.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "*Summary of Significant Accounting Policies*" to our condensed consolidated financial statements included elsewhere in this prospectus.

Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss that may impact our financial position because of adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of exposure resulting from potential changes in interest rates, exchange rates or inflation. We do not hold financial instruments for trading purposes.

Interest rate risk

As of June 30, 2026, we had $34.4 million, in cash, cash equivalents and marketable securities, which consisted of cash, money market funds, and U.S. treasury bills. Our cash and cash equivalents are maintained in accounts with multiple financial institutions in the United States. We may maintain cash and cash equivalent balances in excess of Federal Deposit Insurance Corporation (FDIC) limits. We do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we believe an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. We have the ability to hold our investments until maturity, and therefore, we would not expect our operating results or cashflows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

BUSINESS

Unless the context otherwise requires, references in this section to "we," "us," "our" and the "Company" refer to Obsidian Therapeutics, Inc. following the closing of the Mergers.

Overview

We are a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor infiltrating lymphocyte, or TIL, cell therapies for the treatment of patients with solid tumors. Our proprietary cytoDRiVE™ platform is highly versatile and allows us to leverage drug responsive domains, or DRDs, to control protein function, with our initial focus on TIL cell therapies developed from this platform, or cytoTILs™. Our lead product candidate, amsoki-cel, is a novel, genetically engineered, autologous TIL cell therapy currently in a Phase 2 clinical trial for the treatment of advanced melanoma and a Phase 1 clinical trial for the treatment of non-small cell lung cancer, or NSCLC. Our proprietary cytoDRiVE platform has enabled amsoki-cel to have the potential to drive superior tumor-killing activity with a significantly more tolerable safety profile. In contrast to other TIL approaches, amsoki-cel is designed with regulatable membrane-bound IL15, or mbIL15, which drives TIL persistence, eliminates the need to dose toxic interleukin-2, or IL2, and enables outpatient administration of low-dose lymphodepletion. We currently own or in-license the intellectual property rights to amsoki-cel and own the intellectual property to our proprietary cytoDRiVE platform. Furthermore, amsoki-cel can be manufactured using tumor tissue procurement from an outpatient, minimally invasive core needle biopsy. Across a cohort of fifteen patients with treatment-resistant or refractory melanoma in our Phase 1/2 clinical trial, amsoki-cel administration at the recommended Phase 2 dose demonstrated a 67% confirmed objective response rate, or ORR, and significant tumor burden reduction, including two confirmed complete responses, or CRs. This response rate, to our knowledge, is the highest current ORR shown in this setting across modalities. We believe that, if approved, the more favorable product profile will support rapid market adoption of amsoki-cel relative to currently available TIL cell therapies. Amsoki-cel has been granted Fast Track and Regenerative Medicine Advanced Therapy, or RMAT, designations from the U.S. Food and Drug Administration, or FDA, for the treatment of patients with unresectable or metastatic melanoma that is resistant to immune checkpoint inhibitor, or ICI, therapy. These designations are advantageous to facilitate and expedite the review of therapies, allow for more frequent meetings with FDA to discuss the development plan for the product candidate, and enable potential eligibility for rolling review and priority review, however such designations do not guarantee marketing approval, either on an accelerated basis or otherwise. In our Phase 1 clinical trial in NSCLC, early clinical results show robust tumor shrinkage and include multiple confirmed partial responses, or PRs. We expect to present updated melanoma RP2D data in the fourth quarter of 2026, followed by additional NSCLC Phase 1 clinical data in the first half of 2027 and topline data from our melanoma registration-enabling cohort by year-end 2027. We believe our product candidates are distinct from current cell therapies and have the potential to significantly impact the treatment of solid tumors and clinical outcomes of patients with cancer.

Cell therapies have delivered transformational benefits in treating hematological malignancies; however, their impact in treating solid tumors has been limited. Approved chimeric antigen receptor, or CAR-T, cell therapies or engineered T-cell receptor, or TCR-T, cell therapies, which target single antigens, have demonstrated limited efficacy in solid tumors while leading to significant toxicities. Solid tumors present formidable barriers to immune and cell therapies, including antigen heterogeneity, physical exclusion of immune cells, immunosuppressive tumor microenvironments, and adverse effects due to overlapping expression of tumor targets in tumor cells with non-tumor host cells. Furthermore, while immunotherapies such as ICIs have improved outcomes for patients, more than 85% of cancer patients fail to respond to ICI therapy. As such, solid tumors represent an area of high unmet clinical need, accounting for over 90% of cancer deaths.

We believe that by using TIL, which are immune cells extracted from a patient's own tumor, and our cytoDRiVE platform to develop amsoki-cel, we will be able to overcome the challenges faced by traditional cell therapies. As TIL contain T cells that recognize a broad spectrum of tumor antigens, the potential for loss of antitumor activity

due to antigen heterogeneity is limited. In addition, TIL, being tumor-derived, has an advantage over T cell therapies manufactured from circulating T cells based on their ability to migrate to tumors.

Clinical trials with standard non-engineered TIL, the first generation of TIL cell therapy that involves isolation and expansion of all TIL in the tumor sample, have shown objective responses in clinical trials in limited solid tumor types. Amsoki-cel is an engineered TIL expressing pharmacologically regulatable mbIL15, which has been shown to enhance their cytotoxicity and potentially their persistence.

We have a growing library of internally discovered DRDs of varying sizes and purposes, and our cytoDRiVE platform is designed to enable rapid optimization of tunable and functional proteins. We have developed an extensive synthetic biology engineering toolkit to potentially optimize protein functionality in any cell type, including but not limited to, type I/II membrane proteins, membrane-tethered cytokines, intracellular proteins, secreted proteins, and genome editing proteins. In addition to the development of our cytoTILs, we are exploring the breadth of our cytoDRiVE platform by developing novel approaches that expand its potential applications to additional cell therapies, including the ability to regulate secreted proteins and expression of messenger RNA, or mRNA, or small interfering RNA, or siRNA. cytoDRiVE is highly versatile and can be applied across a broad range of therapeutic applications, including to broaden the reach of cell therapies (including CAR-T) and gene therapies outside of oncology. Our cytoDRiVE platform has led to the development of our lead cytoTIL product candidate, amsoki-cel, with carbonic anhydrase 2, or CA2, as the DRD which is pharmacologically regulated by acetazolamide, or ACZ, to allow for control of mbIL15 expression.

Our Product Candidate: Amsoki-cel

Our lead product candidate, amsoki-cel, is designed to significantly improve upon existing cell therapies, including non-engineered TIL cell therapies, that have demonstrated limited success due to moderate efficacy, unfavorable adverse event profile, and manufacturing challenges. We designed our proprietary manufacturing process to ensure amsoki-cel would contain tumor-reactive TIL with high antitumor activity and phenotypically enriched for expansion and persistence. In addition, we have optimized our manufacturing process across the continuum of pre-Rapid Expansion Protocol, or Pre-REP, activation, transduction of CA2-mbIL15 construct, Rapid Expansion Protocol, or REP, and cryopreservation to potentially allow for robustness, reproducibility, and a high manufacturing success rate. By leveraging our cytoDRiVE and our robust proprietary manufacturing process, we believe amsoki-cel has key attributes required to address the unmet need in the treatment of solid tumors and to meaningfully expand the targetable patient population. These attributes include:

- ***Transduced to express mbIL15***: We utilize ACZ, an oral, FDA approved drug, to regulate the expression of mbIL15 on amsoki-cel. The presence of ACZ, both in our manufacturing process and in patients, stabilizes our mbIL15 construct, allowing it to be expressed on the cell surface where it can activate T cells as well as other immune cells such as natural killer, or NK, cells. This dosing schedule also enables longer term cell persistence. In the absence of ACZ, mbIL15 is degraded by the cell's disposal mechanism, known as the cellular proteasome system.
- ***No IL2 needed during REP nor after TIL infusion*:** Regulated mbIL15 expression drives TIL persistence, eliminating the need for IL2 both during the REP of manufacturing and after TIL infusion. IL2 stimulation of T cells during the REP causes T cell exhaustion, which may translate to reduced T cell persistence after infusion and activation-induced cell death, a form of programmed cell death. Use of IL2 also leads to expansion of regulatory T cells, or Tregs, immune cells that have the potential to suppress T cell cytotoxicity. Further, systemic administration of IL2 has been shown to induce severe toxicities, including capillary leak syndrome with potential for multi-organ failure, myocardial infarction, acute renal failure, and immune-mediated neuropathy.
- ***Utilizes low-dose lymphodepletion*:** Presence of regulated mbIL15 enables the use of low-dose lymphodepletion for amsoki-cel. As compared to non-engineered TIL, treatment with amsoki-cel utilizes approximately 50% less cyclophosphamide and is compatible with outpatient administration.

Standard-dose lymphodepletion has approximately four times more cyclophosphamide than CAR-T regimens and predominantly requires inpatient administration. The administration of standard-dose lymphodepletion and high-dose IL2 in first generation, non-engineered, approved TIL cell therapies further elevates risk of adverse event severity.

- ***More convenient tissue procurement and reduced burden on patients*:** Our clinical data has shown that our optimized manufacturing process allows us to utilize core needle biopsy for tumor tissue procurement, which is an outpatient procedure with minimal scheduling complexity compared to surgical resection.
- ***Manufacturing innovation driving superior phenotype:*** Optimization and innovation of our manufacturing process, including the use of 4-1BB agonism, engineered iFeeder cells, and pharmacologically regulatable mbIL15 creates a drug product that consists of minimally exhausted, memory-rich CD8+ cells. These attributes allow for robust expansion and persistence with enhanced cytotoxicity of amsoki-cel post-infusion into the patient.

Together, we believe the innovation of regulated mbIL15 engineering, along with the proprietary technology and optimization of our manufacturing process, drives a differentiated product profile with a potentially decreased treatment burden for patients, while demonstrating multiple profile advantages over other cell therapies.

In our Phase 1/2 trial, in a cohort of 15 patients with advanced melanoma and confirmed radiological progression post-ICI therapy, an indication of high unmet medical need, treatment with amsoki-cel at the recommended Phase 2 dose, or RP2D, led to an unprecedented ORR of 67% with rapid and durable tumor regression. Furthermore, there was no treatment-related mortality, or TRM, dose-limiting toxicities, or DLTs, or discontinuations due to adverse events. There were no cases of immune effector-cell associated neurotoxicity syndromes, or ICANS. Our optimized regimen enables outpatient administration of low dose lymphodepletion.

Amtagvi®, or lifileucel, was the first TIL cell therapy to receive accelerated FDA approval in 2024 for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if B-Raf proto-oncogene, or BRAF, V600 mutation positive, a BRAF inhibitor with or without a mitogen-activated protein kinase enzyme, or MEK, inhibitor. Amtagvi's approval was based on a 31.5% ORR and the label carries a boxed warning for multiple serious risks, including 7.5% rate of TRM, prolonged severe cytopenia, internal organ hemorrhage, and severe infections. During Amtagvi's registrational clinical trial, capillary leak syndrome occurred in 13.5% and encephalopathy in 17.3% of Amtagvi treated patients. Additionally, grade ≥ 3 febrile neutropenia was seen in 46.8% of patients and 23.6% of patients were transferred to the intensive care unit, or ICU, post-infusion. Many patients in this trial experienced an extended hospital length-of-stay. The boxed warning restricts use of Amtagvi to use only in the inpatient setting with the availability of cardiopulmonary or intensive care specialists. These fatal treatment-related adverse effects are potentially attributed to the multicomponent regimen including standard-dose lymphodepletion and IL2. The amsoki-cel treatment regimen does not include standard-dose lymphodepletion or IL2 and it has a zero rate of TRM and a 10% rate of ≥ Grade 3 febrile neutropenia. Additionally, there have been no cases of capillary leak syndrome or encephalopathy, nor have any ICU transfers occurred among patients with melanoma treated with amsoki-cel.

The U.S. incidence of second-line advanced melanoma is about 10,300 with about 8,500 deaths annually. Our analyses suggest that based on its favorable product profile, amsoki-cel has the potential to double the number of treatment-eligible patients with advanced melanoma compared to existing non-engineered TILs.

The FDA granted amsoki-cel Fast Track and RMAT designations for the treatment of patients with unresectable or metastatic melanoma that is resistant to ICI therapy. Candidates receiving RMAT designation may also be eligible for accelerated approval and priority review. We expect to announce updated melanoma RP2D data in the fourth quarter of 2026. Enrollment is ongoing in our registration-enabling cohort of our existing multicenter Agni-01 study for amsoki-cel in second-line advanced melanoma, with top-line data expected by year-end 2027.

We are also investigating the potential of amsoki-cel as a first-line treatment for advanced melanoma in a dedicated cohort of our ongoing Agni-01 multicenter study. Advanced NSCLC is another attractive indication to pursue with amsoki-cel as it is an immune sensitive tumor with a prevalence approximately ten times greater than that of advanced melanoma. In our Phase 1 regimen optimization NSCLC trial, amsoki-cel has shown reductions in tumor burden, including multiple PRs in patients that had previously been treated with ICI. We believe amsoki-cel has an optimal product profile to drive greater applicability and adoption.

Our Pipeline

We are building an innovative pipeline of genetically engineered TIL cell therapies, led by amsoki-cel, for the treatment of solid tumors. We own worldwide rights to amsoki-cel and our earlier stage product candidates. Our current pipeline is summarized in the diagram below.

Our Strategy

Our goal is to leverage our cytoDRiVE platform to unlock the full potential of cell therapies to treat solid tumors. We believe that our ability to dynamically regulate the activity of our cell therapies in the body using our cytoDRiVE platform is key to achieving this goal. Our strategy is as follows:

- **Advance amsoki-cel for the treatment of melanoma and NSCLC.** Clinical results in patients with second-line advanced melanoma with previous ICI experience provide compelling support for the differentiated antitumor and tolerability profile of amsoki-cel. We expect to announce updated melanoma RP2D data in the fourth quarter of 2026. Enrollment is ongoing in our registration-enabling cohort of our existing multicenter Agni-01 study for amsoki-cel in second-line advanced melanoma, with top-line data expected by year-end 2027. A registration-enabling study is a clinical trial that is intended to obtain sufficient efficacy and safety data to support an NDA or BLA submission to obtain regulatory approval. Although registration-enabling clinical studies are often Phase 3 trials, the FDA has approved drugs based on Phase 2 registration-enabling clinical studies through its accelerated approval program, provided the product is eligible and meets the conditions of accelerated approval. We are also investigating the potential of amsoki-cel as a first-line treatment for advanced melanoma in a dedicated cohort of our ongoing Agni-01 multicenter study. In NSCLC, early clinical results in patients previously treated with ICIs suggest that amsoki-cel has the potential to deliver meaningful antitumor activity in NSCLC while maintaining a generally well-tolerated profile. We intend to continue enrolling patients in our ongoing trial and expect Phase 1 clinical data in the first half of 2027. Similar to melanoma, we believe that the observed tolerability profile of amsoki-cel may provide an opportunity to evaluate the potential of amsoki-cel earlier in the course of disease.
- **Evaluate the potential of amsoki-cel for the treatment of other solid tumors.** Amsoki-cel may be applicable to additional solid tumor types where scientific rationale or prior TIL activity supports development, including tumors with prognostic TIL associations, supportive preclinical findings, or

clinical responses to non-engineered TIL. This rationale extends to tumor types with FDA approved ICI therapies, where endogenous TIL activity is a mediator of response and progression following ICI therapy may indicate exhaustion of TIL function. By leveraging cytoDRiVE and our proprietary manufacturing process, in contrast to what is currently feasible with non-engineered TIL, amsoki-cel may be manufactured from these tumors, whether they harbor suppressed tumor reactive TIL that regulatable mbIL15 may functionally enhance or fewer TIL overall that are potentially expandable in the REP phase leading to robust cell dose yields.

- **Advance our manufacturing capabilities in anticipation of our biologics license application, or BLA, and, if approved, commercial launch.** We believe our proprietary manufacturing process enables advantages in phenotype, yield, process robustness, and tumor procurement flexibility. We collaborate with leading contract development manufacturing organizations, or CDMOs, with cell therapies expertise to manufacture amsoki-cel, and plan to expand our capacity with these partners as we approach potential regulatory approval.
- **Commercialize amsoki-cel in the United States and evaluate partnership opportunities in other regions.** We intend to retain commercial rights to amsoki-cel in the United States and opportunistically evaluate strategic collaborations to maximize the commercial potential of amsoki-cel in other regions.
- **Continue to invest in our cytoDRiVE platform and intellectual property for our cytoTIL product candidates while actively exploring strategic partnerships and collaborations for other applications of our platform.** Our cytoDRiVE platform is designed to be highly versatile and fit-for-purpose, with the ability to drive on- or off-activity across multiple classes of proteins and cell types. We believe there are potential next-generation applications across oncology and broader therapeutic areas. This abundance of potential treatment opportunities may enable us to selectively enter strategic collaborations involving our cytoDRiVE platform to maximize the patient benefit and long-term value of our research and development portfolio.

Our History and Team

Obsidian was founded in 2015 by Atlas Venture to enable a new generation of cell therapies. We are led by a management team with extensive experience in cell therapy, including TIL cell therapies. Madan Jagasia, M.D., our Chief Executive Officer, previously served as Executive Vice President, Medical Affairs at Iovance Biotherapeutics, or Iovance. Prior to Iovance, Dr. Jagasia was Chief Medical Officer and Executive Medical Director of Cancer Patient Care Center, Vanderbilt-Ingram Cancer Center. Parameswaran Hari, M.D., our Chief Medical Officer, has decades of experience leading cell and gene therapy programs. Dr. Hari previously served as Senior Vice President, Clinical Science at Iovance; Chief of Hematology and Oncology at the Medical College of Wisconsin and Secretary of the American Society of Transplantation and Cellular Therapy. Dana Alexander, our Chief Technical Officer, has over 25 years of experience across cell, gene therapy and biologics process development and chemistry, manufacturing, and controls, or CMC, from Phase 1 through commercialization, including serving as Senior Vice President of Technical Operations at AlloVir. Julie Feder, our Chief Financial Officer, has extensive experience in driving the financial and corporate growth of life sciences companies, including serving as Chief Financial Officer for Aura Biosciences, Verastem Oncology, and the Clinton Health Access Initiative.

Background on Solid Tumors and Cell Therapies

Solid Tumors: A Remaining Unmet Need in Cancer

Despite advances across the treatment landscape, solid tumors remain a significant unmet medical need, with mortality and clinical outcomes generally worsening as disease advances. In 2026, there will be an estimated 2.1 million new cancer cases and 600,000 cancer deaths in the United States, with approximately 90% attributable to solid tumors, according to the American Cancer Society. Several key factors such as tumor heterogeneity, as well as challenging tumor microenvironments, have made solid tumors very difficult to treat.

When tumors become refractory to early lines of treatment, options for further therapy are currently limited to alternate forms of chemotherapy, clinical trials of agents in development or palliative care. Each of these alternatives presents a low likelihood of cure, while generally exposing patients to safety and tolerability concerns. As a result, metastatic solid tumors where the disease has progressed after initial therapy continue to account for a disproportionate share of cancer-related mortality.

Characteristics of Existing Cell Therapies

Overview of cell therapies and their limitations

Cellular immunotherapies leverage the innate abilities of immune effector cell, such as tumor trafficking, expansion, and persistence, and address the limitations of conventional cancer treatments. Autologous cell therapies reengineer a patient's own immune system to recognize tumors with high specificity and enable long-term immune surveillance and durable responses. FDA-approved autologous cell therapies have achieved major advances in multiple hematologic malignancies, including B-cell lymphomas, leukemias, and myeloma, as well as in two solid tumor types: metastatic melanoma and synovial sarcoma. Current autologous approaches fall into three primary categories: CAR-T, TCR-T, and TIL cell therapies.

The central challenge for cellular immunotherapies is to achieve cancer-specific cell killing while sparing normal healthy tissues. The immune system distinguishes normal from abnormal cells through two major recognition mechanisms. Antibodies or antibody fragments bind with high specificity to antigens such as cell surface proteins, whereas T cells use their receptors, or TCRs, to detect peptide fragments derived primarily from the breakdown of intracellular proteins and presented on the surface by major histocompatibility complex, or MHC, molecules. Because MHC displays a broad repertoire of intracellular peptides, TCR-based recognition enables deeper surveillance of cellular abnormalities than antibody binding alone. In cancer immunity, professional antigen presenting cells can produce specific cancer directed CD8 T cell responses by presenting tumor-derived antigens derived from dying cancer cells. TIL cell therapies and TCR-T therapies use TCR mediated recognition to mediate cancer cell specific cytotoxicity.

CAR-T cells are engineered T cells that rely on an antibody-derived binding domain to recognize target cells. The antigenic targets of currently available CAR-T therapies reflect the normal cell lineages from which the cancer arose. This approach has had major success in certain hematologic malignancies, where B cell or plasma cell lineage restricted surface antigens such as CD20 or BCMA can be safely targeted because the hematologic system can regenerate itself and thereby tolerate the toxicity arising from temporary off-tumor toxicity. However, in most solid tumors, truly tumor-specific surface antigens are uncommon, increasing the risk of on-target, off-tumor toxicity and limiting the application of CAR-T therapies.

As solid tumors account for approximately 90% of cancer deaths, the lack of tumor specific CAR-T targetable surface antigens reflects a substantial unmet need. Therefore, researchers have continued to investigate ways to redirect T cells, driven by their native TCRs, to recognize and kill tumor cells with greater specificity and reduced off-tumor toxicity. Leveraging the TCR offers the key advantage of enabling immune cells to target intracellular tumor antigens that cannot be accessed by antibody-based approaches or CAR-T cells. Tecelra®, approved by the FDA in 2024, is the first approved engineered TCR therapy. Tecelra recognizes MAGE-A4, an intracellular protein that is generally absent in healthy tissues. However, the potential of TCR-engineered T cell therapies is limited because of two main factors:

1. MHC molecules exist in numerous variants known as allelic variants within individuals and vary extensively between individuals, and each allele presents a distinct peptide repertoire. As a result, TCR therapies can only be administered to patients who express MHC alleles compatible with the engineered receptor.
2. Engineered TCR-T therapies target a single antigen and therefore cannot address the heterogeneity of tumor antigen expression within a tumor. Loss or downregulation of the targeted antigen is a common immune-evasion strategy in cancer which can render the therapy ineffective.

In contrast, TIL cell therapies offer a broader TCR-based approach. By expanding a patient's own tumor-derived T cell population, which naturally recognizes a diverse set of intracellular peptides presented by MHC, TIL offer a breadth of antigen recognition, reduces vulnerability to single-antigen loss and are not subject to MHC allele restriction constraints of TCR-T therapies.

Table 1 below summarizes certain characteristics of existing cell therapy modalities, including CAR-T, TCR-T and non-engineered TIL cell therapies, and highlights key differences in targeting, safety considerations and practical limitations.

	CAR-T Therapy	TCR-T Therapy	Non-Engineered TIL Cell Therapy
Advantages	• Target antigens beyond peptides on cell surface independent of MHC • Lower cumulative cyclophosphamide dose in lymphodepletion regimen compared to non-engineered TIL cell therapy	• Accessibility to intracellular target through MHC • Utilizes natural TCR signaling pathways for potentially better effect • Lower cumulative cyclophosphamide dose in lymphodepletion regimen compared to non-engineered TIL cell therapy	• Broad repertoire of TCRs that target both defined and undefined tumor antigens • Because TIL are isolated from tumors, they are enriched with T cells that specifically recognize tumor cells and have demonstrated the ability to traffic to, and survive in, the tumor microenvironment
Disadvantages	• Limited availability of truly tumor-exclusive surface antigens and antigen heterogeneity in solid tumors can limit efficacy and increase on-target/off-tumor toxicity risk • Evasion by loss of target antigen surface expression	• Treatment limited by HLA type • Target single antigens and may not address antigen heterogeneity within a single tumor • Can cross-react with off-target peptides in healthy tissues and cause toxicities • Evasion by loss of antigen presentation machinery can render the therapy ineffective	• Require surgical tumor resection for T cell isolation and cause delays in generating TIL • Need for IL-2 dosing • Higher cumulative cyclophosphamide dose in lymphodepletion regimen

	CAR-T Therapy	TCR-T Therapy	Non-Engineered TIL Cell Therapy
		• Some TCR-Ts require IL-2 dosing	

	CAR-T Therapy	TCR-T Therapy	Non-Engineered TIL Cell Therapy
Target Antigen	Lineage-specific surface antigens also expressed by normal cells (e.g., CD19, BCMA)	Intracellular tumor-associated antigens bound to MHC (e.g., NY-ESO-1, MAGE-A4)	Neoantigens or tumor-associated antigens bound to MHC
Tumor Cell Specificity	Low	High	High
HLA Restriction	No	Yes	No
Tumor Types	Hematological malignancies (e.g., B-cell leukemia, lymphoma) Solid tumors with limited efficacy	Solid tumors and hematological malignancies	Solid tumors, including melanoma, NSCLC, ovarian, cervical and sarcoma
Toxicity	Cytokine release syndrome (CRS), neurotoxicity	Off-target effects, CRS	Lymphodepletion and IL-2-related toxicities

TIL cell therapy for the treatment of solid tumors

One of the earliest demonstrations of the antitumor potential of cell therapies came from the work of Steven Rosenberg, M.D., Ph.D. and colleagues at the National Institutes of Health in the 1980s, before the discovery of ICIs. These researchers found that TIL from melanoma patients could be expanded *ex vivo* in cell culture to boost their antitumor activity. TIL cell therapy offers a way to potentially avoid the limited effectiveness of CAR-T therapies in solid tumors while taking advantage of the ability of the TCR to more specifically recognize tumor cells. Because TIL are isolated from tumors, they are enriched with T cells that specifically recognize tumor cells and have demonstrated the ability to traffic to, and survive in, the tumor microenvironment. Furthermore, TIL contain polyclonal T cells that are capable of recognizing a spectrum of tumor-specific antigens that may be present in any given tumor.

The first FDA-approved TIL cell therapy, Amtagvi, received accelerated approval in 2024 to treat patients with unresectable or metastatic melanoma who have been previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. Amtagvi was approved based on 31.5% ORR, including three complete responses. The median overall survival, or OS, from a follow-up analysis of patients in this trial was 13.9 months, with a five-year OS of 19.7%.

The limitations of current TIL cell therapies

Traditional TIL cell therapies, such as Amtagvi, which use TIL that are not genetically modified, have a number of limitations that result in increased morbidity and mortality. These include:

- **Manufacturing challenges.** Non-engineered TIL cell therapies require that tumor tissue be obtained by surgical resection. The need for an invasive surgical procedure poses challenges such as ensuring a patient is eligible for anesthesia and surgery and ensuring availability of specialized surgeons (e.g. thoracic surgeons) for the area of surgical biopsy. These requirements result in significant tumor tissue harvest delays because it requires scheduling with a surgeon trained in the appropriate specialty. Furthermore, the number of TIL generated using these processes is not always sufficient to deliver effective therapy to patients. Of the 111

patients who underwent tumor resection in the Amtagvi registrational trial, 22 (20%) were not infused with Amtagvi for clinical or manufacturing reasons. Of the 89 patients who were infused, seven patients were excluded from the primary efficacy analysis because their infused product did not meet product specification or comparability criteria. An additional nine infused patients received Amtagvi at a dose below the lower bound of the recommended dosing range of 7.5 x 10 viable cells. Thus, 34% of patients were not included in the primary efficacy population within the recommended dosing range.

- **Use of IL2 for *ex vivo* TIL expansion.** IL2 is a powerful cytokine that critically affects the features and effectiveness of T cells. IL2 drives T cell expansion and leads to their ability to maximally secrete interferon gamma, or IFNγ, in response to antigen stimulation. Hence, IL2 is used throughout the manufacturing process for non-engineered TIL, including the REP. However, IL2 stimulation of T cells during the REP can cause T cell exhaustion and may translate to reduced T cell persistence after infusion. Use of IL2 also leads to expansion of Tregs which have the potential to suppress T cell cytotoxicity. Although the use of IL2 during the REP can drive rapid expansion of TIL, the cytotoxicity of the expanded product may be compromised.
- **Need for lymphodepletion.** Treatment with non-engineered TIL cell therapies requires that the patient first undergo standard lymphodepletion, which is generally administered using fludarabine and cyclophosphamide. Lymphodepletion serves a number of purposes including eliminating potentially suppressive endogenous T cells, reducing suppressive cytokines, and creating a regenerative immune niche that administered cells could colonize. It has been shown that lymphodepletion is essential for cellular immunotherapies of cancer. However, not all patients are eligible to undergo standard lymphodepletion. Because individuals with poor organ function, poor performance status or active infections are ineligible for the standard lymphodepletion procedure, these individuals are unable to receive non-engineered TIL cell therapies.
- **Requirement for inpatient IL2 dosing after TIL infusion.** In conventional TIL regimens, physicians administer several doses of high-dose IL2 intravenously in the inpatient setting after delivering TIL cells. For this to be effective, high doses of IL2 are required due to the lower affinity of the IL2 receptor on cytotoxic T cells. High dose IL2 has been associated with life-threatening adverse events, such as capillary leak syndrome, hypotension and tachycardia.

Our Solution: Amsoki-cel

Overview

We are advancing amsoki-cel, an engineered cytoTIL cell therapy for the treatment of advanced melanoma and NSCLC. Amsoki-cel was developed using our proprietary cytoDRiVE platform technology and designed to overcome the limitations of existing therapies. A key differentiating feature of amsoki-cel is the introduction of a genetic construct that encodes a mbIL15 protein whose expression can be regulated using ACZ, an orally available FDA approved drug. The expression of IL15 by amsoki-cel eliminates the need for IL2 in the treatment regimen in both the REP phase of manufacturing and inpatient treatment. In a cohort of 15 patients with advanced melanoma and confirmed radiological progression post-ICI therapy, treatment with amsoki-cel at the RP2D led to an ORR of 67% with rapid and durable tumor regression. Also notable is that robust antitumor responses were obtained using low dose lymphodepletion and, in some patients, with core needle biopsies instead of surgical resections. There was no TRM and there were no DLTs or discontinuations due to adverse events. Amsoki-cel has Fast Track and RMAT designations from the FDA for the treatment of patients with unresectable or metastatic melanoma that is resistant to ICI therapy. In our Phase 1 clinical trial in NSCLC, early clinical results show robust tumor shrinkage and include multiple confirmed PRs.

Enrollment is ongoing in our registration-enabling cohort of our existing multicenter Agni-01 study for amsoki-cel in second-line advanced melanoma, with top-line data expected by year-end 2027. ***Engineering Amsoki-cel with mbIL15***

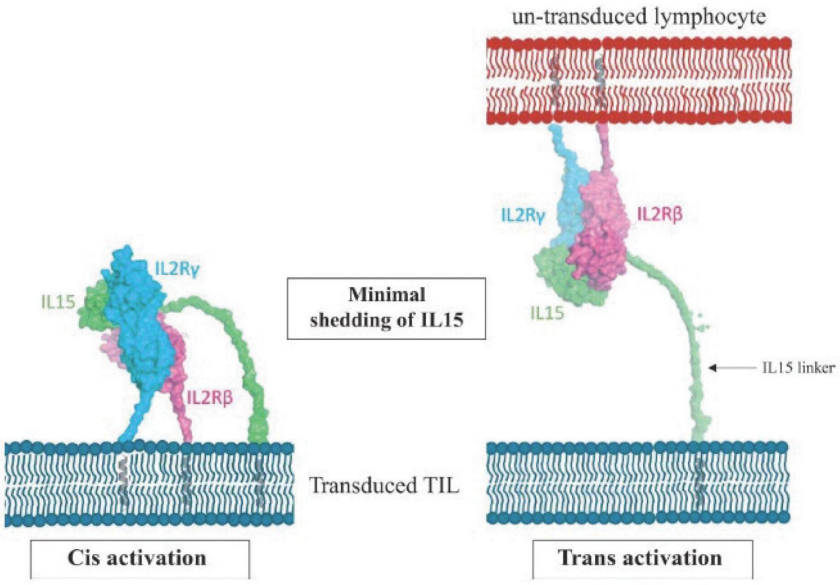
By utilizing our cytoDRiVE technology and incorporating mbIL15 into amsoki-cel, we are able to eliminate the need for IL2 in the treatment regimen. IL15 and IL2 are structurally related cytokines that share common receptor subunits. Similar to IL2, IL15 expands cytotoxic T cells and NK cells. Unlike IL2, IL15 does not preferentially expand Tregs, which are associated with an immunosuppressive tumor microenvironment. A further advantage of IL15 is that it promotes survival and maintenance of long-lived memory CD8 T cells, including subsets with stem-cell like properties. By contrast, IL2 leads to higher activation of short-lived effector T cells which are predisposed to terminal exhaustion both during manufacturing and *in vivo* after infusion.

Whereas IL2 has been approved by the FDA for the treatment of cancer, notwithstanding its association with significant toxicities, no systemic IL15 therapy has received FDA regulatory approval to date. Clinical experience with the administration of exogenous soluble IL15 found that it led to robust T cell proliferation, but its therapeutic benefit was limited with no responses among patients with melanoma. Additionally, a number of severe toxicities were observed including hypotension, thrombocytopenia and elevated liver enzymes. These limitations have prevented the clinical development of soluble exogenous IL15 in a therapeutic context. To leverage the benefits of IL15 while avoiding these undesired effects, amsoki-cel has membrane bound expression of IL15 with its levels regulated via our cytoDRiVE platform.

Amsoki-cel is engineered to express a proprietary IL15 construct with two key features:

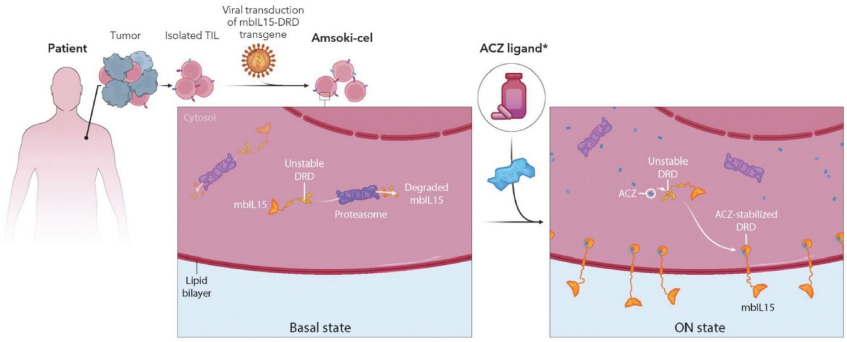
- IL15 is anchored to the membrane through a flexible linker, or mbIL15. The linker of mbIL15 has been engineered to avoid shedding of mbIL15 and thereby limit systemic exposure. Further, the linker length was optimized such that mbIL15 possesses the ability to both act *in cis* to directly activate transduced TIL cells, as shown in Figure 1 below (blue, left panel), and *in trans* to activate other immune cells such as NK cells shown in Figure 1 below (red, right panel). Figure 1. mbIL15 activation of TIL and NK cells.

Figure 1. mbIL15 activation of TIL and NK cells.



- **The expression of mbIL15 is regulated by ACZ, an orally available FDA-approved drug**. Our mbIL15 construct was designed to be regulated by cytoDRiVE. In the absence of ACZ, known as the "basal state" in the left panel in Figure 2 below, the DRD is degraded in the cell by the proteasome, thus limiting mbIL15 expression. As shown on the right panel of Figure 2 below, cytoDRiVE regulation enables the CA2-DRD construct to be stabilized in the presence of a paired ligand, ACZ, which enables dose-dependent, reversible mbIL15 expression on the TIL cell surface. ACZ is a CA2 inhibitor that functions as a diuretic for the treatment of edema and elevated intraocular pressure and is used to treat altitude sickness. It has been used in the clinic for over fifty years. This ability to alter the expression of mbIL15 using an oral drug is designed to dynamically regulate its expression to achieve an appropriate balance between efficacy while minimizing potential adverse events. Should a patient's lymphocytes expand more than desired which may be associated with certain toxicities, mbIL15 expression can be suspended by stopping ACZ administration.

Figure 2. Regulation of mbIL15 activity using ACZ.

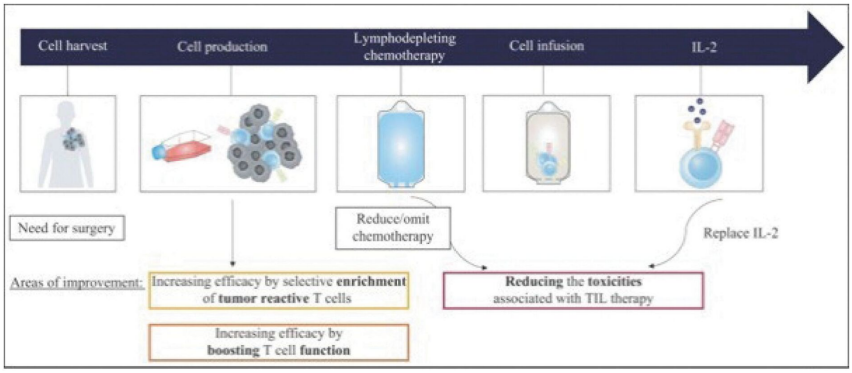


Our Proprietary Manufacturing Process

We designed our manufacturing process to ensure amsoki-cel would contain tumor-reactive TIL with high antitumor activity and phenotypically enriched for expansion and persistence. In addition, we have optimized our manufacturing process across the continuum of Pre-REP, activation, transduction of CA2-mbIL15 construct, REP, and cryopreservation to potentially allow for robustness, reproducibility and a high manufacturing success rate. Our manufacturing process for amsoki-cel delivers consistently robust cell yield and high process consistency with a greater than 95% demonstrated success rate. By leveraging our cytoDRiVE platform and our proprietary manufacturing process, we believe amsoki-cel has key attributes required to address the unmet need in the treatment of solid tumors and to meaningfully expand the targetable patient population.

Figure 3 below summarizes the various challenges in the manufacturing process of non-engineered TIL cell therapies and illustrates the potential opportunities to expand access and improve outcomes.

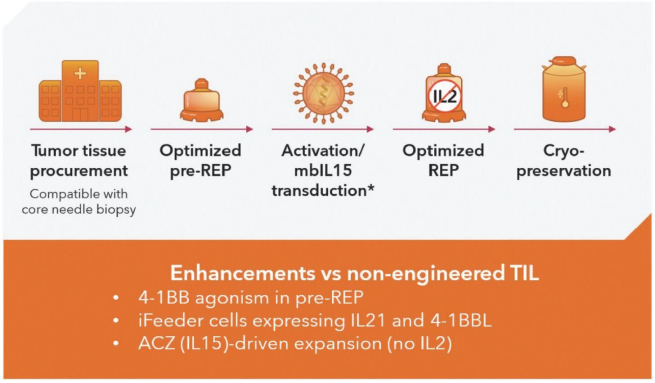
Figure 3. Manufacturing process of non-engineered TIL cell therapies.



Our manufacturing process can be divided into five stages, as summarized in Figure 4 below:

- **Tissue acquisition.** Amsoki-cel is a patient-specific product that requires isolation of TIL from a patient's tumor. We have used tumor tissue, both from surgical resections or from minimally invasive core needle biopsies to manufacture amsoki-cel in our clinical trials with no differential impact on cell dose or product phenotype. An advantage of core needle biopsies is that they can typically be obtained in an interventional radiology procedure under local anesthesia, which is faster than surgical excision. Surgical procedures may delay treatment by several weeks due to the need to coordinate schedules with a surgeon, anesthesiologist and operating room.
- **Pre-REP.** In Pre-REP stage, we isolate the TIL from the tissue sample and treat them with an antibody that serves as an agonist for 4-1BB. This process optimization has been shown to increase TIL expansion, enrich for putative tumor-specific clones and enhance antitumor cytotoxicity.
- **Activation and transduction.** We transduce the patient's TIL with a genetically inactivated viral vector containing our CA2-mbIL15 construct and activate them using a CD3 antibody.
- **REP.** The expansion stage of TIL cell therapy manufacturing process typically involves two components: IL2 and feeder cells. We do not use IL2 in this stage to generate amsoki-cel and instead induce expression of our mbIL15 construct using ACZ. Also, whereas the feeder cells used to generate other TIL cell therapies consist of irradiated allogeneic peripheral blood mononuclear cells, or PBMCs, from healthy donors, amsoki-cel is manufactured using an irradiated engineered cell line that expresses both IL21 and 4-1BB ligand, or iFeeder cells, and use of this cell line improves our ability to expand TIL to generate amsoki-cel with a more favorable phenotype while reducing the cost and variability associated with using donor PBMCs. These REP process modifications drive further amplification of the CD8+ memory rich T cell phenotype.
- **Cryopreservation.** Through optimization of our processes, we are able to cryopreserve amsoki-cel while maintaining potency. This provides us with the ability to ship our finished drug product from central manufacturing facilities to treatment centers.

Figure 4. Overview of the amsoki-cel *ex vivo* manufacturing stages.



* Anti-CD3 Ab; retroviral vector

Melanoma Disease Background

Melanoma is the fifth most common malignancy in the United States and the most lethal form of skin cancer. The National Cancer Institute estimates that there were approximately 105,000 diagnoses of melanoma and approximately 8,500 deaths from melanoma in the United States in 2025. While most patients diagnosed with localized melanoma have an excellent prognosis, advanced melanoma is associated with widespread metastasis and has a five-year survival rate of only 34.6%.

The primary risk factor for developing melanoma is exposure to ultraviolet light, including sunlight and tanning beds. Ultraviolet light and other environmental insults can cause DNA damage, which in turn leads to an increased rate of mutations. Melanoma is one of the most highly mutated cancers. It has frequent driver mutations, such as mutations in the gene for BRAF, that directly contribute to tumorigenesis, as well as a wide array of passenger mutations, which accumulate but do not directly alter the propensity of the tumor to grow or spread. These mutations, both driver and passenger mutations, are a differentiating feature between melanoma cells and healthy cells that have led to the development of a number of therapies.

In patients who are diagnosed early and have few cancerous lesions, surgical excision can lead to long-term cures. In patients with more advanced and metastatic disease, unfortunately, surgical treatment has more limited benefit. Two types of systemic therapies are commonly used to treat these patients: ICIs and inhibitors of the BRAF pathway. Other approved systemic therapies, including combinations that target multiple immune checkpoints, have further expanded options for select patients.

Multiple immunotherapies including inhibitors of the PD-1/PD-L1 and CTLA-4 checkpoints have been approved to treat metastatic melanoma. These groundbreaking therapies have changed the treatment landscape for metastatic melanoma and dramatically improved both response and survival rates for patients. Treatment of patients with previously untreated unresectable melanoma with a combination of nivolumab and ipilimumab had an ORR of 58% and a median OS of 72.1 months. Grade 3/4 treatment-related AEs were reported in roughly 55% of patients, including 41.5% of patients with Grade 3/4 immune-related AEs.

Despite the immense improvement of survival upon ICI therapy, a significant subgroup of metastatic melanoma patients see no tumor response or subsequently lose initial response. Up to 60% of patients treated first-line with PD-1 monotherapy and up to 40% of those treated with PD-1 plus CTLA-4 combination do not respond to ICI treatment. 72% of patients do not respond to second-line CTLA-4 plus ICI combination therapy in the post ICI setting.

Approximately half of cutaneous melanomas have a mutation in the BRAF gene resulting in constitutive or always-on BRAF activity, which in turn promotes cancer cell proliferation. Treatment with inhibitors of BRAF has been shown to lead to an OS rate of about 70% at one year. Combination therapy using a BRAF inhibitor and a MEK inhibitor provides additional suppression of BRAF signaling and delays the development of resistance resulting in a slight increase in OS to about 75% at one year. However, responses to BRAF and MEK inhibitors have limited durability because resistance typically develops at around twelve months post-treatment.

Treatment options remain limited for patients with melanoma who are refractory to or have relapsed following treatments such as ICI and BRAF inhibitors. In recent years, additional therapies have been approved for certain patients in this setting, including Amtagvi and, more recently, Replimune's Tudriqev in combination with nivolumab. In 2024, Amtagvi, the first FDA-approved TIL cell therapy, received accelerated approval for the treatment of these patients. The ORR in a single-arm open-label trial of Amtagvi in 73 patients was 31.5%. Non-engineered TIL, including Amtagvi, have multiple safety and logistical challenges, including regimen complexity and inpatient resource utilization, that impact broader adoption.

NSCLC Disease Background

Globally, an estimated 1.8 million people die of lung cancer each year. It is the leading cause of cancer-related death, accounting for approximately 18% of all cancer deaths. There were an estimated 227,000 new cases of lung cancer diagnosed and 125,000 deaths in the United States in 2025. NSCLC is the most common subtype of lung cancer, accounting for approximately 80 to 85% of lung cancers. The treatment paradigm for NSCLC has significantly changed over the past few years. Previously patients were primarily treated with radiation therapy or combinations of cytotoxic drugs. Recent developments have led to the emergence of targeted therapies based on alteration in the genes for epidermal growth factor receptor, or EGFR, and anaplastic lymphoma kinase gene, or ALK, and ICI for those without actionable gene mutations.

Prior to the introduction of ICI, the five-year OS rate for patients with metastatic NSCLC was approximately 5%. Current standard of care front-line treatment for patients with metastatic NSCLC and no targetable mutations consists of ICI therapy alone or in combination platinum-based chemotherapy with ICI with or without anti-angiogenic therapy; however, response rates are at between 48% to 58% based on histologic subtype. Even if achieved, responses are generally short-lived, and durable responses are relatively uncommon. Standard treatment after progression on ICI-based treatment typically entails single-agent chemotherapies, which have modest response rates (approximately 16%), and are typically not durable (median progression free survival, 2.9 months). An unmet need thus continues to exist for patients with metastatic NSCLC without actionable mutations whose disease is relapsed or refractory to ICI-based treatments. Similarly, in the case of patients with targetable mutations, the unmet need is for effective and safe therapy after the mutation targeted agents are no longer effective.

Clinical Trials with amsoki-cel

We are conducting Agni-01, an ongoing, multicenter Phase 1/2 clinical study evaluating cryopreserved amsoki-cel in patients with advanced solid tumors, including melanoma and NSCLC. In melanoma, dose optimization has established our recommended Phase 2 dose with encouraging antitumor activity observed in patients, and Phase 2 enrollment is ongoing to support a potential registrational path. In NSCLC, dose escalation through dose level three, or DL3, has been completed, with continued regimen optimization underway to inform a Phase 2 study. Collectively, our results to date demonstrate clinical activity supporting continued advancement of amsoki-cel in melanoma and NSCLC.

Clinical antitumor activity

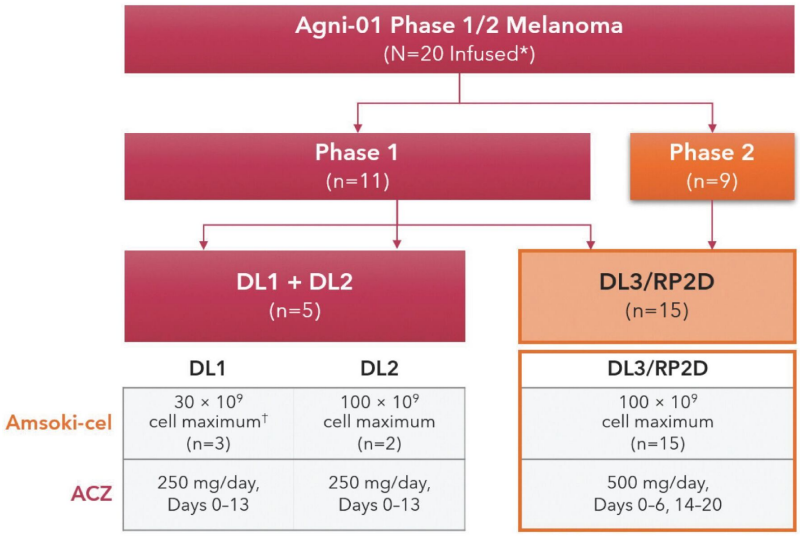
Melanoma

Amsoki-cel was first tested in the clinic in a first-in-human Phase 1 trial initially with fresh non-cryopreserved (n=8) and then cryopreserved (n=9) amsoki-cel product at The University of Texas M.D. Anderson Cancer

Center. This study treated 17 patients with advanced melanoma who had relapsed or who were refractory to ICI therapy. After lymphodepletion, patients received a single intravenous infusion of amsoki-cel followed by oral treatment(s) with ACZ to drive the expression of mbIL15 using our cytoDRiVE technology. The Phase 1 trial was designed to optimize the cell dose cap of amsoki-cel as well as the dosing regimen of ACZ. The primary and secondary endpoints for this trial were safety and tolerability of amsoki-cel and investigator-assessed preliminary efficacy, respectively, and both endpoints were met. Despite the exploratory nature of this trial, an ORR of 40%, including two CRs, was observed in the first ten evaluable patients, providing strong evidence of the antitumor potential of amsoki-cel. The safety profile indicated no DLTs or Grade 4 nonhematologic treatment related adverse events and three Grade 3 nonhematologic treatment-emergent adverse events in two patients (abdominal pain, ALT elevation, syncope) and no substantive difference between fresh and cryopreserved products.

We then initiated Agni-01, a multicenter, company-sponsored Phase 1/2 trial of cryopreserved amsoki-cel in patients with treatment relapsed or refractory advanced melanoma. We identified three parameters to further optimize in the Phase 1 portion of this trial: the maximal number of amsoki-cel cells to be infused; the daily and cumulative dose of ACZ; and the dosing schedule for ACZ. As shown in Figure 5 below, in the DL1 cohort, which consisted of three patients, amsoki-cel dose was capped at 30 × 109 cells and ACZ 250 mg daily for up to 14 days. In DL2, which consisted of two patients, amsoki-cel dose was capped at 100 × 109 cells and ACZ 250 mg daily for up to 14 days. DL3, which consisted of 15 patients across the Phase 1 and Phase 2 arms, targeted amsoki-cel dose cap of 100 × 109 cells and ACZ 500 mg daily for two 7-day periods (Week 1 and Week 3), separated by a 7-day break with no ACZ. Patients in DL3 received 7 days of ACZ at 6-week intervals starting approximately at week 5-6. In addition, for patients in DL1, DL2 and DL3, protocol guided treatment consisted of additional 7-day periods of ACZ at 6 week intervals starting approximately weeks 5 to 6. DL3 was found to lead to maximal TIL expansion in patients while minimizing toxicities and was chosen as the recommended Phase 2 dose, or RP2D.

Figure 5. Design of the Agni-01 Phase 1/2 trial in melanoma.



Ten of the fifteen patients treated with DL3 / RP2D dosing achieved either a complete (n=2) or partial response (n=8), resulting in an ORR of 67%. We believe that the demonstrated frequency of antitumor responses observed to date with amsoki-cel is attributable to both our mbIL15 cytoDRiVE engineering and our differentiated manufacturing processes.

Amsoki-cel treatment was associated with significant antitumor activity across these 15 patients with ongoing responses in eight patients as of January 22, 2026 (~18 weeks median follow-up). Of note, robust antitumor activity was observed using amsoki-cel created from surgical resections as well as from core needle biopsies independent of the anatomic site of tumor procurement or doses manufactured and infused. We believe that the ability to use core needle biopsies for patients as the source of their TIL provides the opportunity to significantly shorten the time from the decision of the clinician to treat with amsoki-cel to the ability to deliver the manufactured product to patients. We believe core needle biopsies will further enhance adoption and improve patient outcomes with increased operational efficiency relative to approaches that typically rely on surgical tumor resection. Our optimized regimen enables outpatient administration of low dose lymphodepletion. All the melanoma patients treated with amsoki-cel at the RP2D had four-day low dose lymphodepletion regimen consisting of cyclophosphamide 750 mg/m2/day for three days and Fludarabine 30 mg/m2/day for four days. On average, this lymphodepletion regimen represents an approximate 50% reduction in cyclophosphamide dose.

NSCLC

The Agni-01 trial is currently evaluating the potential of various dosing regimens of amsoki-cel in both melanoma and NSCLC as summarized in Figure 6 below. In our NSCLC cohort, one patient received amsoki-cel at DL1, one patient at DL2 and four patients at DL3. The patients treated at DL3 could not tolerate similar ACZ dosing intensity as in melanoma DL3 patients due to inflammatory pulmonary toxicity or pneumonitis leading to ACZ withdrawal. We addressed this issue by introducing an intermediate cell dose cap of 60 billion cells. At this dose cap, the tolerability issues due to ACZ were alleviated. In addition, we have augmented the extended ACZ redosing regimen and dosed patients with ACZ for seven days every other week after week three. By contrast, in the melanoma DL3 cohort, ACZ was administered every six weeks beyond week three.

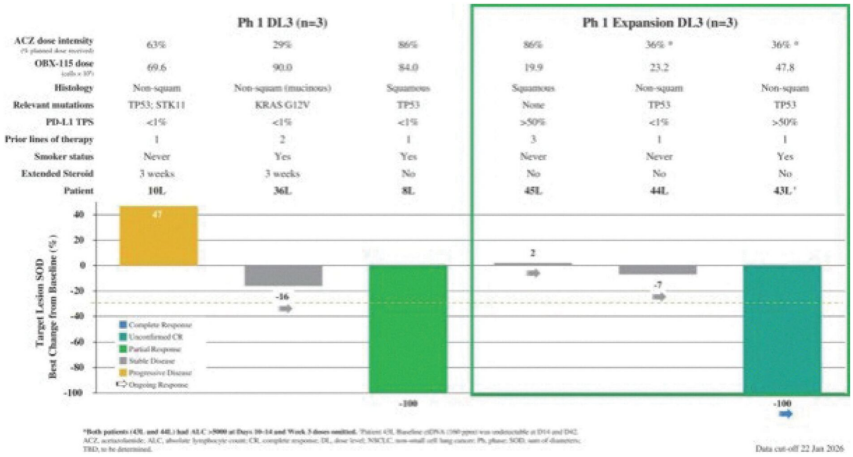
Figure 6. Melanoma and NSCLC patient dosing in the Agni-01 trial.

Infused Patients		Melanoma		NSCLC
Dose Level		Phase 1 (N=11)	Phase 2 (N=9)	Phase 1 (N=10)
DL1	30B cell dose cap ACZ: 250 mg/day, Days 0–13 Planned 28-day cumulative dose: 3500 mg ACZ redosing every 6 wks starting approx. wk 6	3	0	1
DL2	100B cell dose cap ACZ: 250 mg/day, Days 0–13 Planned 28-day cumulative dose: 3500 mg ACZ redosing every 6 wks startin approx. wk 6	2	0	1
DL3	100B cell dose cap ACZ: 500 mg/day, Days 0–6, 14–20 Planned 28-day cumulative dose: 7000 mg ACZ redosing every 6 wks startin approx. wk 6	6	9	4
	DL3 Expansion in NSCLC: **Intermediate cell dose cap (~60B)** ACZ: 500 mg/day, Days 0–6, 14–20 Planned 28-day cumulative dose: 7000 mg + Extended ACZ redosing every other wk	NA	NA	4

We have also modified the low-dose lymphodepletion regimen used with amsoki-cel in NSCLC to include a single dose of gemcitabine which enables a further 66% reduction in cyclophosphamide dose as compared to the current low dose lymphodepletion with the intent of improving tolerability. Optimization of dosing and treatment regimen are still under investigation in NSCLC.

Of the six efficacy evaluable patients across both DL3 regimens shown in Figure 7 below, there were two cases where rapid tumor shrinkage was observed by week six. In patient 43L (DL3 intermediate cell dose cap), levels of circulating tumor DNA, or ctDNA, were undetectable on day 14 and day 42. Three patients who received an intermediate cell dose of amsoki-cel did not require prolonged corticosteroid dosing for inflammatory adverse events, they demonstrated lymphocyte expansion in peripheral blood and were able to receive augmented longitudinal ACZ redosing.

Figure 7. Initial antitumor activity in NSCLC patients treated with amsoki-cel.



Safety and tolerability

Melanoma

In all trials observed to date, amsoki-cel was generally well-tolerated with no TRM, DLTs or discontinuation due to AEs. In addition, no cases of immune effector-cell associated neurotoxicity syndromes, or ICANS, or capillary leak syndromes have been observed. The most frequently reported events are consistent with the reversible myelosuppression expected with lymphodepletion or electrolyte abnormalities secondary to the known diuretic effect of ACZ, all of which were managed with standard of care supportive measures. Adverse events considered specifically associated with amsoki-cel were predominantly low-grade and responsive to protocol-guided ACZ interruption, dose adjustment, or with supportive treatment.

NSCLC

In ten Phase 1 NSCLC patients infused with amsoki-cel, there was no TRM. Expected differences from melanoma were consistent with disease pathophysiology and co-morbidities associated with lung cancer. Consistent with the underlying pulmonary comorbidities, the primary distinction was Grade ≥3 pneumonitis, occurring in three patients (30%), with all cases resolving prior to discharge. One subject in DL3 experienced

Grade 3 ICANS, which resolved to baseline following protocol directed management. Grade 3 cytokine release syndrome, or CRS, was observed in four patients (40%). Additional frequent or severe adverse events were aligned with reversible lymphodepletion-related myelosuppression or laboratory changes attributable to the known diuretic effects of ACZ.

Established AE Profile of Non-engineered TIL

Melanoma

The Amtagvi label carries a boxed warning for multiple serious risks, including a 7.5% rate of TRM, prolonged severe cytopenia, internal organ hemorrhage, and severe infections. Amtagvi requires the use of high dose IL2, which has been associated with risks including capillary leak syndrome and neurologic toxicities. Capillary leak syndrome occurred in 13.5% and encephalopathy in 17.3% of Amtagvi treated patients. During Amtagvi's registrational clinical trial, grade ≥ 3 febrile neutropenia was seen in 46.8% of patients and 23.6% of patients were transferred to the intensive care unit, or ICU, post-infusion. Many patients in this trial experienced an extended hospital length-of-stay. The boxed warning restricts use of Amtagvi to use only in the inpatient setting with the availability of cardiopulmonary or intensive care specialists. These fatal treatment-related adverse effects are potentially attributed to the multicomponent regimen including standard-dose lymphodepletion and IL2.

NSCLC

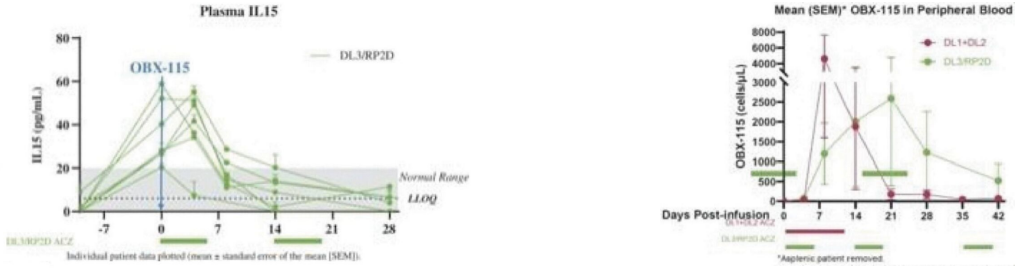
The largest dataset on non-engineered TIL safety in NSCLC comes from the FDA's review of 59 patients treated with the lifileucel regimen (as part of the Amtagvi BLA assessment). Grade ≥4 respiratory disorders occurred more frequently in NSCLC than in melanoma cohorts (15.3% vs. 6.9%). In addition, about 12% of NSCLC patients died from respiratory complications within 30 days of starting treatment. Two additional patients died of hemophagocytic lymphohistiocytosis. Other notable adverse events included febrile neutropenia (28.8%) and dyspnea (52.5%).

Pharmacodynamic evidence for the role of mbIL15 in amsoki-cel treatment

The pharmacodynamic features of amsoki-cel, including the nature of mbIL15 that limits shedding to avoid systemic exposure, and the regulatable nature of mbIL15 due to the optimized ACZ dose and schedule drives the early expansion and persistence of amsoki-cel in patients after infusion, and may potentially explain the favorable AE profile.

Amsoki-cel is designed to express mbIL15 using our cytoDRiVE drug-regulated expression technology, which we believe is a key aspect of our safety and tolerability profile. Levels of soluble IL15 were elevated at the time of amsoki-cel administration as expected due to lymphodepletion and persisted for the subsequent several days. As shown in the left panel in Figure 8, each line in the graphic is representative of a patient with melanoma, the presence of elevated levels of IL15 in plasma at the time of the first administration of amsoki-cel and ACZ is consistent with its induction as a response to lymphodepletion. There was no correlation between activation of mbIL15 expression with ACZ and levels of IL15 in plasma. One of the benefits of lymphodepletion before administration of TIL cell therapy is the reduction in immune suppressor cells which have the potential to counteract the TIL antitumor activity. Another factor that contributes to the importance of lymphodepletion to the success of immune cell therapies is a surge in cytokines, in particular IL15 that occurs in response to immune activation caused by lymphodepletion-related cell death. There was no evidence that mbIL15 expression contributed to IL15 in plasma.

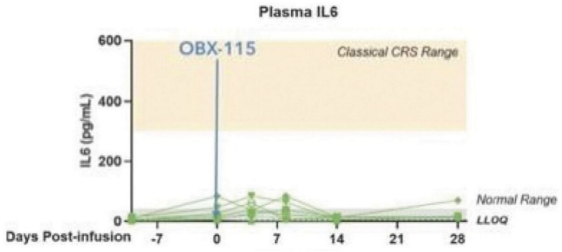
Figure 8. In patients with melanoma, treatment with amsoki-cel and ACZ does not lead to an increase in IL15 levels in plasma (left panel), and amsoki-cel at RP2D persisted in peripheral blood for 42 days (right panel).



As shown in the right panel in Figure 8, we observed that the persistence of amsoki-cel in peripheral blood was higher using the RP2D dosing regimen in which the two initial seven day periods of ACZ were separated by a week. This dosing regimen enabled a higher overall dose of ACZ to be delivered, which was better tolerated than the continuous two-week dosing regimens in DL1 and DL2. These results demonstrate the regulated expression of mbIL15 using our cytoDRiVE technology without causing high systemic plasma IL15 levels after amsoki-cel infusion and ACZ administration. Consistent with the longer persistence of amsoki-cel, we observed higher antitumor activity in patients with melanoma who received the RP2D dose than DL1 or DL2.

As shown in Figure 9 below, patients with melanoma dosed with amsoki-cel and then treated with two seven-day periods of ACZ separated by a week of no treatment did not experience elevations in serum levels of IL6, a cytokine that serves as a biomarker of classical CRS caused by other immunotherapies. Therefore, the treatment of CRS occurring with amsoki-cel is different than those occurring with CAR-T therapies and with T-cell engagers, and does not warrant the use of tocilizumab. Treatment may involve transient interruption in ACZ dosing and/or short course of corticosteroids as guided by the protocol.

Figure 9. In patients with melanoma, treatment with amsoki-cel and ACZ does not lead to an increase in IL6 levels in plasma.



Clinical Development Strategy for amsoki-cel

Melanoma

We commenced enrollment in the registration-enabling cohort of our existing multicenter Agni-01 study for amsoki-cel in second-line advanced melanoma, with topline data expected by year-end 2027.

Based on our RMAT designation and Iovance's precedent with Amtagvi, as well as the data we have generated in our ongoing Phase 2 trial, we believe that a convincing argument could be made for the FDA to set us on a path toward potential accelerated approval of amsoki-cel in advanced melanoma. A registration-enabling study is a clinical trial that is intended to obtain sufficient efficacy and safety data to support an NDA or BLA submission to obtain regulatory approval. Although registration-enabling clinical studies are often Phase 3 trials, the FDA has approved drugs based on Phase 2 registration-enabling clinical studies through its accelerated approval program, provided the product is eligible and meets the conditions of accelerated approval.

We plan to enroll approximately 100 patients in a registration-enabling cohort in the existing multicenter study in melanoma and expect data from this trial by year-end 2027. The registration-enabling cohort will be a single-arm open label study in patients with advanced melanoma progressing after immune checkpoint inhibitor-based therapy with blinded independent reviewer assessed ORR as the primary endpoint. Secondary endpoints include safety, duration of response (DOR), progression-free survival (PFS) and overall survival (OS).

Given the tolerability and antitumor activity observed to date in melanoma, we believe that there is potential for amsoki-cel to be used as a first-line treatment as well. We intend to evaluate this by enrolling a cohort of patients in this setting in our ongoing Phase 2 melanoma trial.

NSCLC

In NSCLC, we continue to enroll patients in our Phase 1 trial, and we expect additional clinical data to become available in the first half of 2027. Our current trial in NSCLC is focused on patients who have previously been treated with ICI. The primary endpoint is the incidence of dose limiting toxicities, and investigator-assessed ORR is a secondary endpoint.

We believe that the observed treatment burden of amsoki-cel compared to other TIL cell therapies may provide an opportunity to evaluate the potential of amsoki-cel earlier in the course of disease.

Market Opportunity

Melanoma

Advanced melanoma remains a significant driver of mortality despite substantial therapeutic advances. A large fraction of patients treated with frontline ICIs develop primary or acquired resistance to ICIs, resulting in a meaningful pool of patients requiring additional lines of treatment.

Based on market research that we commissioned, we estimate that approximately 10,000 patients in the United States were eligible for second-line treatment of unresectable or metastatic melanoma in 2023. Not all patients in this pool are appropriate candidates for cell therapies, and real-world attrition is driven by (i) adequate baseline fitness and health status, (ii) disease progression that allows sufficient time to complete the treatment journey, and (iii) access to a qualified caregiver, resulting in an estimated cell therapy treatable population of approximately 65% of this patient subgroup. Within this cell therapy treatable population, additional factors further narrow eligibility for TIL cell therapies, including ability to tolerate lymphodepletion, feasibility of tumor procurement via surgical resection or core needle biopsy, and clinical stability during the manufacturing and scheduling period.

Currently, an estimated 25% of 2L+ melanoma patients are eligible to receive Amtagvi; however given amsoki-cel's potentially differentiated profile we believe we will be able to address around 50% of these same patients. Amtagvi, the only approved TIL cell therapy for patients with unresectable or metastatic melanoma previously treated with an ICI, had an ORR of 31.5%. Meanwhile, we observed a 67% ORR in advanced melanoma with amsoki-cel. In addition, the antitumor activity of amsoki-cel has been associated with a low rate of serious adverse events including no cases of TRM or capillary leak syndrome. We believe the need to use high doses of cyclophosphamide for lymphodepletion and high dose IL2 limits the number of patients who are eligible to receive Amtagvi.

We believe there is an opportunity for amsoki-cel to deliver significant clinical benefit in the large population of patients who have previously been treated with ICI. The tolerability of amsoki-cel, as well as the ability to create amsoki-cel using core needle biopsies and to deliver an outpatient administration of low-dose lymphodepletion provide the potential to advance our medicine into earlier lines of therapy, an option that is not as readily available for current therapies with significant toxicities and treatment challenges.

A key limitation for cell therapies has been the inability to scale both the manufacturing and the number of clinical sites where the therapy is available. In addition to our current CDMO that is supporting our ongoing clinical trials, using our expertise we collaborate with CDMOs to scale our manufacturing capacity not only for clinical trials but for our subsequent commercialization. We believe these efforts will allow us to provide improved patient and physician experience through reliable treatment delivery and broader site activation. We have learned from the launch of Amtagvi that there is a viable path to bringing TIL cell therapy to market. Iovance has already qualified 85 treatment centers across the United States to treat patients with Amtagvi. By Iovance's estimate, 95% of addressable patients are within 200 miles of a treatment center qualified to treat patients with TIL cell therapy and there are more than 85 treatment centers as of December 31, 2025. Amtagvi has achieved rapid market access across 250 million covered lives, mostly covered by private payers with 3-week financial turnaround, and recommendation by the National Comprehensive Cancer Network. The expansion of qualified centers and demonstrated commercial uptake indicate that the operational and reimbursement framework for TIL cell therapy delivery is becoming increasingly established.

NSCLC

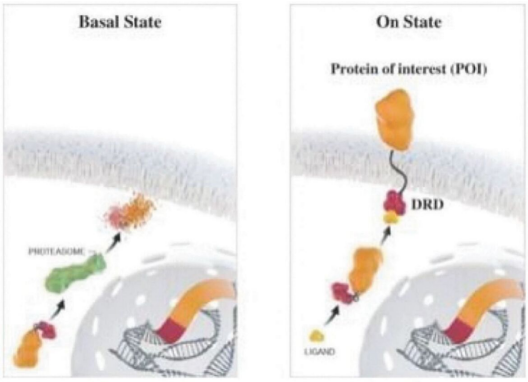
There were an estimated 227,000 new cases of lung cancer diagnosed and 125,000 deaths in the United States in 2025. NSCLC is the most common subtype of lung cancer, accounting for approximately 80 to 85% of those cases. Some patients will progress to the later stages of the disease, and other patients already have locally advanced or metastatic disease at the time of diagnosis. There are approximately 90,000 patients with advanced/metastatic NSCLC per year. Current standard of care front-line treatment for patients with metastatic NSCLC and no targetable mutations consists of single-agent ICI therapy or combination platinum-based chemotherapy with ICI or anti-angiogenic therapy. Most patients receiving ICI therapy do not have durable responses. Standard treatment after progression on ICI-based treatment typically entails single-agent chemotherapies, which have modest response rates (approximately 16%), and are typically not durable (median PFS, 2.9 months). For example, in a randomized Phase 3 trial in previously treated metastatic NSCLC, docetaxel demonstrated an objective response rate of 12.8%. Even incremental improvements in overall response rate and durability of responses could be clinically meaningful, especially relative to first-line treatment responses in other settings like melanoma. There are approximately 36,000 patients who will progress into the second line setting representing a significant unmet need for more efficacious therapies that can deliver durable responses, especially for chemotherapy-free alternatives with superior tolerability. Given the substantially larger incidence, we believe the commercial opportunity in advanced NSCLC is up to 5 times larger than that of advanced melanoma. If approved, we believe we will be able to leverage our manufacturing infrastructure and commercial capabilities, initially from our melanoma program, to drive significant market adoption of amsoki-cel for the treatment of NSCLC.

Our cytoDRiVE Platform—a Key Component of Our Next Generation Therapies

A key element of our cytoDRiVE platform is the ability to express mbIL15 in amsoki-cel and to dynamically regulate its expression in patients. cytoDRiVE is designed to leverage the tendency for intracellular misfolded and unstable proteins to be degraded by the cellular proteasome system. To build cytoDRiVE constructs, we create mutant versions of small molecule binding domains that are stable in the presence of their ligands but have a propensity to be degraded in their absence. Through the fusion of one of these binding domains, which we refer to as DRD, to a protein of interest, such as mbIL15, we impart the ability to control expression of the protein of interest by a small molecule ligand. While no immunogenicity or safety issues have been detected with CA2 and mbIL15 (DRD-protein pairing) in amsoki-cel clinical or laboratory studies to date, the potential for immunogenicity or other serious side effects have not yet been studied for other future DRD-protein pairs. By carefully selecting the DRD, we can use FDA-approved, orally available drugs to control the stability of our cytoDRiVE constructs. We believe that this makes cytoDRiVE a flexible, multipurpose approach for delivering regulators of expression of proteins.

As illustrated in Figure 10 below, in absence of ligand binding, the unstable DRD (red) is recognized by the cellular unfolded protein system and the DRD and fused protein of interest (orange) are targeted for degradation, eliminating the expression of the protein of interest. In the presence of a small molecule ligand (yellow), the DRD is stabilized, avoiding degradation and allowing the protein of interest to be expressed.

Figure 10. Ligand-dependent regulation of the cellular unfolded protein system.



In amsoki-cel, we fused a CA2 DRD to a proprietary mbIL15 construct. The CA2 DRD was engineered with mutations to reduce its stability in the absence of ligand binding. We use ACZ, an FDA approved oral CA2 inhibitor, with no known anti-neoplastic activity as a stabilizing ligand to regulate mbIL15 expression on the cell surface of amsoki-cel. ACZ is generally well-tolerated, penetrates the blood brain barrier and has a favorable pharmacokinetic profile. It does not interfere with T cell function and is widely available as a generic product.

Next Generation Cellular Therapies: Future Oncology Applications of our cytoDRiVE Platform

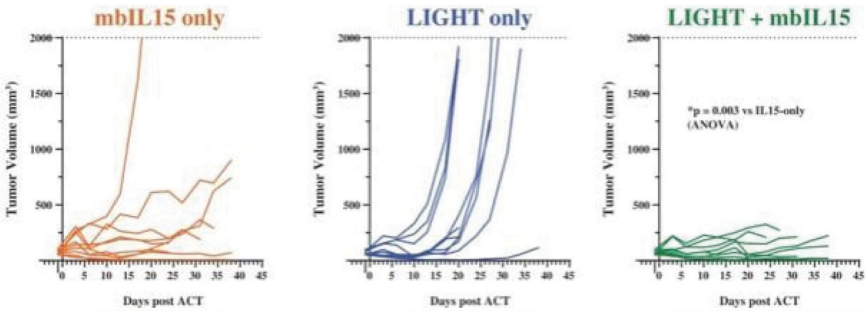
We are actively exploring future applications of our cytoDRiVE platform to enhance the ability of our product candidates to treat less TIL infiltrated (colder) tumors. Two examples from our early-stage research programs illustrate the application of cytoDRiVE to enhance immune-cell antitumor activity, including co-regulated expression of Lymphotoxin-like, inducible, competes with herpesvirus glycoprotein D for HVEM, a receptor expressed by T lymphocytes, or LIGHT, and mbIL15, and spatio-temporal regulation of IL12 using T cell

activation dependent elements. Further, we believe the flexibility of our platform may allow cytoDRiVE to be incorporated into a range of engineered immune cell therapies beyond TIL and potentially into other non-oncology settings where controlled protein expression is desirable. We are evaluating collaboration and partnership opportunities to continue development of these promising early-stage research programs.

Regulated expression of LIGHT and mbIL15

LIGHT is a member of the tumor necrosis factor super family, or TNFSF, that interacts with the lymphotoxin beta receptor, or LTbR, and regulates the formation of lymphoid organs. In preclinical studies, LIGHT expression within a tumor has been linked to the formation of tertiary lymphoid structures and vascular normalization, both of which are associated with favorable prognosis in many tumor types. Figure 11 below shows the application of cytoDRiVE to develop cytoTIL15-LIGHT cells, where the CA2 DRD co-regulates both mbIL15 and LIGHT. In a fibrotic tumor model where non-engineered TIL are unlikely to show benefit, co-expression of mbIL15 and LIGHT upon induction with ACZ leads to better tumor control compared to mbIL15 or LIGHT alone.

Figure 11. Dual regulated expression of LIGHT and mbIL15 inhibited growth in a fibrotic colon cancer model.



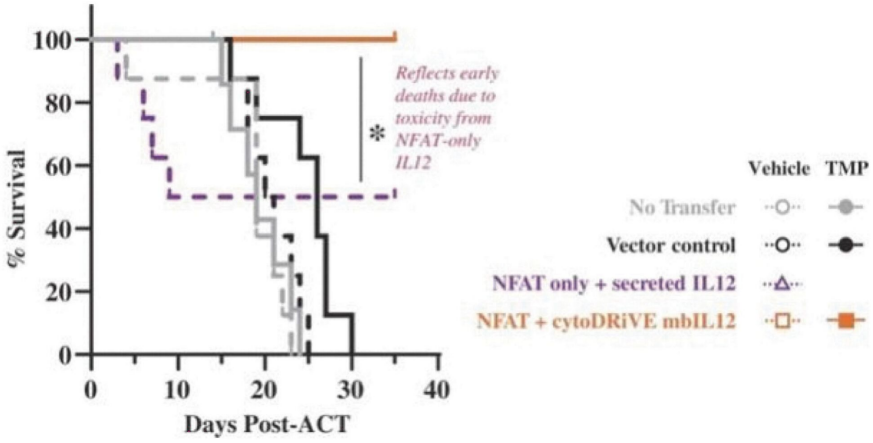
Spatial and temporal regulation of IL12

IL12 is a potent cytokine known to remodel immunosuppressive tumor microenvironments and promote antitumor immunity through diverse innate and adaptive immune mechanisms. Early clinical trials in the mid-1990s showed that systemic delivery of IL12 incurred dose-limiting toxicities.

We combined our cytoDRiVE technology with NFAT-dependent transcription to enable the ability to temporally control mb-IL12 expression following T cell recognition of tumor (spatial regulation). In these cells, the expression of a cytoDRiVE construct containing the gene for mbIL12 fused to DRD is under control of an NFAT responsive promoter, a genetic element that drives transcription only upon activation of T cells, such as when T cells recognize tumor. Only upon T cell activation is the IL12/DRD fusion protein synthesized, but is rapidly degraded if the DRD ligand is not present, providing a second level of control.

We assessed the tolerability and antitumor activity of this construct in a B16-F10 tumor model in mice as shown in Figure 12 below. Survival in this model with no treatment was between 20 and 25 days. Treatment with control T cells increased survival by a few days in both the untreated mice (gray in the figure below) or control-treated mice (black in the figure below). Treatment with NFAT (only) regulated expression of soluble IL12 (purple in the figure below) resulted in early mortality for half of treated mice due to toxicities associated with IL12. Treatment with cells engineered with our NFAT/cytoDRiVE mbIL12 led to 100% survival to the end of the study at day 35 (orange in the figure below).

Figure 12. Spatial and temporal regulation of IL12 increased survival in a B16-F10 tumor model.



Potential Applications of our CytoDRiVE Platform Outside of Oncology

While our current focus is on the application of cytoDRiVE to enhance the antitumor activity of cell therapies, potential applications of cytoDRiVE are not limited to specific classes of proteins of interest or to particular cell types. cytoDRiVE technology has the potential to broaden the reach cell therapies and for diseases outside of oncology, such as autoimmune disorders. By enabling temporal control of protein activity or expression with activation-dependent regulatory elements, cytoDRiVE is designed to provide controlled expression of potent cytokines or other immune-modulating proteins. We believe this flexibility may allow cytoDRiVE to be incorporated into a range of engineered immune cell therapies beyond TIL and potentially into other non-oncology settings where controlled protein expression is desirable.

Manufacturing

We do not own or operate GMP manufacturing facilities for the production of amsoki-cel and currently have no plans to build our own clinical or commercial GMP manufacturing capabilities. We have a proprietary manufacturing process and collaborate with leading CDMOs to manufacture amsoki-cel and, if we receive regulatory approval, we intend to rely on such third parties for commercial GMP manufacture. Our manufacturing process for amsoki-cel consistently delivers a robust cell yield with a greater than 95% demonstrated manufacturing success rate in meeting the current product release criteria. These release criteria often evolve based on increased manufacturing experience and based on regulatory input. This may affect the manufacturing success rate over time. We believe our manufacturing capacity strategy will support drug supply for our future clinical trials and commercial demand for amsoki-cel for the treatment of advanced melanoma, if approved. We do not have long-term supply agreements, and we purchase our required drug product on a development manufacturing services agreement or purchase order basis. 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 have personnel with significant technical, manufacturing, analytical, quality, regulatory, including cGMP, and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes.

Our product candidates for clinical trial use must be manufactured in compliance with cGMP regulations. The cGMP regulations include requirements relating to personnel, buildings and facilities, equipment, control of

components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products.

Commercialization

We have exclusive commercial rights to our product candidates globally. Given our stage of development, we have not yet established a commercial organization or sales and distribution capabilities. A key challenge for cell therapies, such as amsoki-cel, is the ability to scale both the manufacturing and the number of clinical sites where the therapy is available. We have transferred our expertise and knowledge to CDMOs, which manufacture amsoki-cel for our clinical trials and will also do so for commercialization, if approved by FDA.

We plan to independently commercialize our products, if approved, in the United States and other regions where we determine it makes commercial sense to do so. At the appropriate time, we will build the required commercial infrastructure including recruiting a sales force and a medical affairs team. As product candidates advance through our pipeline, our plans may change.

Competition

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities, and other research institutions. Ultimately, the diseases our product candidate and any future product candidates target, and for which we may receive marketing authorization, will determine our competition. Our product candidate, if approved, will have to compete with existing therapies and new therapies that may become available in the future. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We believe the key competitive factors affecting the success of our product candidate, amsoki-cel, if approved, are likely to include efficacy, safety, manufacturing, treatment logistics, patient eligibility, physician adoption, and the availability of reimbursement.

Patients with melanoma are treated using a range of therapeutic approaches, including surgery, radiation therapy, chemotherapy, targeted therapies, ICIs, biologic therapies such as monoclonal antibodies, and emerging

immunotherapies, including cell-based therapies. Accordingly, we believe amsoki-cel, if approved, would face competition from pharmaceutical, biotechnology and other companies developing therapies for cancer, including for patients with melanoma or NSCLC whose disease has progressed following prior treatment with checkpoint inhibitors and chemotherapy. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. We may compete with other cell therapy or immunotherapy companies such as Iovance Biotherapeutics Inc. (Amtagvi), Replimune Group, Inc., AbelZeta Inc., Biosyngen Pte Ltd, GRIT Biotechnology Co., Ltd., Shanghai Juncell Therapeutics Co., Ltd., Immatics N.V., Immunocore Holdings plc, Intima Bioscience, Inc., KSQ Therapeutics, Inc., Marker Therapeutics, Inc., TILT Biotherapeutics Ltd, and others. In addition, numerous compounds are in clinical development for cancer treatment. Any of these compounds may prove to be safer, more effective, more convenient, more broadly applicable or more commercially successful than our product candidates.

Intellectual Property

We strive to protect and strengthen our proprietary platforms and technologies, product candidates, inventions, improvements, and other intellectual property that are commercially relevant to the success of our business by, among other things, acquiring, maintaining, and defending patent rights, whether developed internally or licensed from third parties, and preserving the confidentiality of our trade secrets and know-how. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Additional regulatory protection may also be available via data exclusivity, market exclusivity, and patent term extensions on a jurisdiction-by-jurisdiction basis. Our commercial success may depend, in part, on our ability to protect and strengthen the intellectual property rights relevant to our proprietary platforms and technologies, and to operate without infringing on any valid and enforceable third-party intellectual property rights.

The patent position of most biopharmaceutical companies is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation, resulting in court decisions, including U.S. Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. Because of this, some of our current and future patent applications may not result in patents being issued. Additionally, the laws of foreign countries may not protect our rights to the same degree as the laws of the United States, or vice versa.

As of March 1, 2026 our owned and in-licensed patent portfolio from the Board of Regents of the University of Texas System consists of 7 granted US patents, 20 pending US patent applications, 28 foreign granted patents and 91 pending foreign patent applications. As of March 1, 2026, we have 26 registered trademarks and 4 pending trademark applications. Additionally, we have had no outstanding litigation related to our intellectual property nor any threat to initiate claims against us. Our owned patents, patent applications and licensed intellectual property from the Board of Regents of the University of Texas System on behalf of M.D. Anderson cover various aspects of our programs and technology, including our cytoDRiVE platform and amsoki-cel as further described herein. Owned patents and patent applications include composition of matter and methods of making and using various aspects of the cytoDRiVE platform and amsoki-cel. We have issued patents in the United States, Japan, Singapore, Korea, Mexico, Australia, Europe, Canada, and China and pending applications in those and other jurisdictions such as Israel, and India. The intellectual property licensed from M.D. Anderson includes amsoki-cel, specifically around the manufacturing process and know-how. Under the M.D. Anderson License Agreement, ownership of improvements is determined based on inventorship. In particular, the licensed intellectual property represents one component of our broader development program. Specifically, we currently rely in part on the in-license from M.D. Anderson for the development and commercialization of amsoki-cel, but we are not materially dependent on the license from M.D. Anderson for our continued development and commercialization efforts for amsoki-cel. We do not believe the termination of the M.D. Anderson License Agreement would materially delay our currently planned development timelines for amsoki-cel. In addition, we believe we would otherwise mitigate any immaterial impact of such a termination. For additional information about the M.D. Anderson License Agreement, please see the sections titled "*Rest of the World Government Regulation-M.D. Anderson License Agreement*", "*Management's Discussion and Analysis of Financial Condition*

and Results of Operations of Obsidian-License and Collaboration Agreements-Collaboration and License Agreement with University of Texas M.D. Anderson Cancer Center" and Notes 9 and 10 to the Consolidated Financial Statements of Obsidian.

In the future, there may be the need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how or to defend against claims of infringement of the rights of others. Litigation is costly and could divert our attention and resources from other business functions and responsibilities. Furthermore, even if we were to prevail and our patents were found to be valid and infringed, a court could refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such compensation could be insufficient to adequately offset the damages to our business caused by the infringer's competition in the market. Furthermore, adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses and/or pay significant royalties to such third parties and could also prevent us from manufacturing, selling or using our product, platform, or technologies, any of which could severely harm our business.

Although we rely on intellectual property rights as well as contractual protections to establish and protect our proprietary rights, we believe that factors such as the technological and creative skills of our personnel, the discovery of new solutions, features and functionality, and ongoing enhancements to our platform are also essential to establishing and maintaining our competitive and technological advantage.

We control the access to and use of our proprietary platforms, technologies, and other confidential information through the use of internal and external controls, including contractual protections with employees, contractors and partners. Our employees, consultants and other third parties are required to enter into confidentiality and proprietary rights agreements with us and we control and monitor access to our proprietary technology, documentation, and other confidential information. We require all employees and independent contractors to sign agreements assigning to us any inventions, trade secrets, works of authorship, developments, processes and other intellectual property generated by them on our behalf and under which they agree to protect our confidential information. In addition, as needed, we enter into confidentiality agreements with our partners.

Government Regulation and Product Approval

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, safety, effectiveness, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing.

Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory authority before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory approvals and the subsequent compliance with federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates biological products, or biologics, under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, requirements, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board or ethics committee before a clinical trial commences;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations as well as international standards for good clinical practice, or GCP, and any additional requirements for the protection of human research patients and their health information, to establish the safety, purity and potency of the proposed biological product for its intended use;
- submission to the FDA of a biologics license application, or BLA, seeking marketing approval with such application providing substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current good manufacturing practice regulations, or cGMPs, and, if applicable, cGTPs,to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA to confirm compliance with GCPs and data integrity, among other things; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted and clinical trials are initiated. An IND is an exemption that allows a biological product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer a biological product candidate to humans. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate's IND at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight at the local level as set forth in the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result

from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an Institutional Biosafety Committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, companies and other institutions not otherwise subject to the NIH Guidelines may voluntarily follow them.

Clinical trials involve the administration of the biological product candidate to subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their *www.clinicaltrials.gov* website. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for some time. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. Manufacturers or distributors of biological product candidates being developed for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to expanded access requests.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product candidate is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the biological product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The biological product candidate is evaluated in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for the specific targeted diseases or condition and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population, generally at geographically dispersed clinical trial sites, and to generate enough data to statistically evaluate the efficacy and safety of the biological product candidate for approval. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product approval.

In addition, post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory authorities require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials and other developments related to the IND must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the trial's investigators for serious and unexpected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar product, findings from, animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction over that listed in the clinical protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days after the sponsor's initial receipt of the information.

In addition, during the development of a new biological product, sponsors are given opportunities to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach alignment on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the product candidate.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements, and cGTP requirements, as applicable. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the biological product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials, all required testing of a biological product candidate in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the biological product candidate for one or more indications. FDA approval of a BLA must be obtained before commercial marketing of the biological product begins. The BLA must include results of all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from Company-sponsored clinical studies intended to test the safety and effectiveness of the use of the product candidate, or from a number of alternative sources, including studies initiated by independent investigators.

Under the Prescription Drug User Fee Act, or PDUFA, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for approved and marketed biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a submitted BLA to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. If the submission is accepted for filing and substantive review, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the filing date. In both standard and priority reviews, the review process may also be extended, such as by the sponsor's submission of a major amendment, which extends the goal date by three months.

The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent for the proposed indication, and the facility in which it is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will generally inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements, and cGTPs, as applicable, and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the FDA decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. Should the FDA determine that the data supporting the application are inadequate to support approval, the FDA may issue the complete response letter without first conducting required inspections, testing submitted product lots, or reviewing proposed labeling. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if additional data and information are submitted following receipt of a complete response letter, the FDA may decide that the BLA does not satisfy the criteria for approval. In September 2025, the FDA began publishing complete response letters soon after issuing them to the respective sponsors, breaking with long standing agency tradition of publishing complete response letters with approval documentation after the product is approved.

When the FDA determines the sponsor's BLA and the biological product candidate meet the standards for approval, it will issue an approval, or licensure, letter. If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS

is a safety strategy to manage a known or potential serious risk associated with a biological product and to enable patients to have continued access by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized, and may further limit marketing of the product based on the results of these post-marketing studies.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same approved use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity, or where the original applicant cannot produce sufficient quantities of product. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same approved use or indication, or the same drug or biologic for a different approved use or indication. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they

are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. As part of the fast track program, the FDA may review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if the biological product candidate is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the FDA, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the FDA for review during the pre-approval review period. Further, under FDORA, the FDA must specify the conditions for any post-approval trials by the date of accelerated approval and the agency has flexibility in setting forth such conditions, which may include enrollment targets, clinical trial protocol and milestones–including the target date of trial completion.

In addition, following a request from the sponsor, the FDA may grant breakthrough therapy designation to a biological product candidate for its indication under study. Breakthrough therapy designation is intended to expedite the development and review of products that are intended to treat serious or life-threatening conditions and that preliminary clinical evidence demonstrates that the biological product candidate, alone or in combination with other drugs and biologics, shows substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the

sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, though the same biological product candidate may be eligible for these other expedited pathways if relevant criteria are met.

The FDA may also designate a product candidate as a regenerative medicine advanced therapy, or RMAT. The RMAT designation is intended to facilitate an efficient development program for, and expedited review of, any product candidate that meets the following criteria: (i) the product candidate qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the product candidate is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review of BLAs. Cell therapy candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate. RMAT-designated cell therapy candidates that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the completion of clinical studies, patient registries, or through submission of other sources of real world evidence (such as electronic health records), through the collection of larger confirmatory data sets, or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

In 2025, the FDA created a new voucher program called the Commissioner's National Priority Voucher, or CNPV pilot program, with the goal of radically expediting therapeutic product review and approval processes. The agency may award a CNPV to a company or a specific biological product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date. The FDA has further indicated that a CNPV can expire, and the voucher process must be commenced within two years following receipt from the FDA.

None of these programs changes the standards for approval but they may expedite the development or approval process. Even if a biological product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

The FDA defines "rare pediatric disease" as a (i) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (ii) a rare disease or condition within the meaning of the Orphan Drug Act. Designation of a biological product candidate as a product for a rare pediatric disease does not guarantee that a marketing application for such biological product candidate will meet the eligibility criteria for a rare pediatric disease priority review voucher, or PRV, at the time the application is approved. The FDA may determine that a marketing application for any such product candidates, if approved, does not meet the eligibility criteria for a PRV. Vouchers for rare pediatric disease drugs are awarded for qualifying applications when the drug receives approval. Under current law, after September 30, 2029, the FDA may not award any rare pediatric disease priority review vouchers, although the FDA's authority to do so could be extended by Congress in the future.

Post-Approval Requirements

Biological products are subject to pervasive and continuing regulation by the FDA after approval, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, providing the FDA with updated safety and efficacy information, product sampling and distribution, and advertising and promotion of the product.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements to ensure the long-term stability of the product and its continued safety, efficacy, purity, and potency. cGMP regulations require among other things, quality control and quality assurance as well as the

corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMPs, and cGTPs, as applicable. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer must submit samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA may conduct laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. Systems need to be put in place to record and evaluate adverse events reported by health-care providers and patients and to assess product complaints. An increase in severity or new adverse events can result in labeling changes or product recall. Defects in manufacturing commercial products can result in product recalls.

The FDA may withdraw approval of a BLA if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Manufacturers and other parties involved in the supply chain for prescription biological products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved label to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, FDA Form 483s, warning letters, or untitled letters;
- Partial or full clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims that are in accordance with the provisions of the approved label. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of products for uses or inpatient populations that are not described in the product's approved labeling (known as off-label use). Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for biological products. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, (e.g., the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local government agencies. For example, our business practices, including our clinical research program and any

future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, transparency requirements, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving 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 purchasing, leasing, ordering or arranging for the purchase, lease or order of any 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. The term remuneration has been interpreted broadly to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The AKS is an intent-based statute; however, it has been interpreted to cover any arrangement in which a single purpose of the remuneration is to pay for referrals or to induce future referrals. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The federal civil and criminal false claims laws, including the False Claims Act, or FCA, which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health-care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. 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 FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery.

The federal Health Insurance Portability and Accountability Act of 1996, or 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), imposes requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in

federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

We may also become subject to federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs under federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Many states and foreign jurisdictions have laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, 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 that 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; and state and local laws requiring the registration of pharmaceutical sales representatives.

There are significant compliance costs associated with ensuring business arrangements with third parties comply with applicable healthcare laws and regulations. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed

healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services.

Factors payors consider in determining reimbursement are based on whether the product is:

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

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our biological product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, significant legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of biological product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell biological product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible

beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (a requirement later replaced under the Inflation Reduction Act of 2022, or the IRA, by the Medicare Part D manufacturer discount program); and

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Both the Trump administration and Congress have indicated that they will continue to seek new legislative and executive measures to control drug costs. In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year that remain in effect through 2031.
- The U.S. American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting in 2025 absent further legislation.
- The IRA also includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program (regardless of the number of orphan designations) provided that the drug is only approved for rare disease indications. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet known.
- The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to apply significant funding pressure on state Medicaid budgets, decrease the number of persons enrolled in Medicaid, and reduce the services covered by Medicaid.
- In February 2026, President Trump signed into law several pharmacy benefit manager, or PBM, regulatory reforms as part of a federal budget package, including but not limited to requirements for PBMs to pass back 100% of rebates and fees to commercial health plan sponsors; to provide extensive informational disclosures related to patients' coverage and benefits; and to accept only bona fide service fees from drug companies when providing services under Medicare Part D. Additionally, the Department of Labor, or DOL, also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under the Employment Retirement Income Security Act. If finalized as proposed, the DOL rule would also allow plan fiduciaries to audit those

PBM disclosures to confirm accuracy. Significant efforts to change the PBM industry as it currently exists may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biological product developers like us.

Recent executive and regulatory actions include President Trump's 2025 executive orders directing HHS to pursue most-favored-nation, or MFN, pricing targets for prescription drugs and to evaluate reforms under the Inflation Reduction Act, including potential elimination of the so-called "pill penalty" that subjects small molecule drugs to Medicare price negotiation four years earlier than biologics. Additional regulatory actions taken include a voluntary MFN-based framework for Medicaid manufacturers and two proposed CMS rules that would introduce MFN pricing principles into Medicare Part B and Part D reimbursement, respectively, with implementation currently anticipated to begin as early as 2026, though legal challenges could delay or modify these proposals. The scope, timing, and ultimate impact of these and any further actions remain uncertain, and if implemented, such measures could adversely affect the pricing, reimbursement, and commercial viability of our biological product candidate, if approved.

Individual states have also been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health-care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health-care programs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services. We expect additional state, federal and foreign healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for health products, which could result in reduced demand for our products, if approved or additional pricing pressure.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the GDPR imposes strict requirements for processing the personal data of individuals within the EEA, including requirements relating to processing health-related and other sensitive data, establishing a legal basis for processing such as obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, imposing limitations on retention of personal data; maintaining a record of data processing, complying with the principal of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit and

taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA to countries that the EU does not consider to have in place adequate data protection legislation, including the United States. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. Further, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and remains under review by the Commission during this period. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reform of UK data protection laws following Brexit. There is a risk that any material changes which are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Additional Regulation

In addition to the foregoing, state, federal and foreign laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Foreign Government Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products.

Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-Clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union, or EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, as set forth in EU Directive 2004/10/EC. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCPs, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for EU member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

The CTR introduced a centralized process for the submission and review of clinical trial authorization applications, which allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU member state in which the clinical trial is to be conducted, leading to a single decision per EU member state. The application must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the application has been harmonized as well, including a joint assessment by all EU member states concerned, and a separate assessment by each EU member state with respect to specific requirements related to its own territory, including ethics rules. Each EU member state's decision is communicated to the sponsor via the centralized EU portal. Once the application is approved, clinical study development may proceed.

Medicinal products used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or cGMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a marketing authorization application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product.

- "Centralized MAs" are issued by the European Commission through the centralized procedure following an opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs (i.e. gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health in the EU.

- "National MAs" are issued by the competent authorities of individual EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any EU member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days, excluding clock stops, where a medicinal product is of major interest from a public health perspective. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant an MA, which is issued within 67 days of receipt of the EMA's recommendation. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed.

Furthermore, an MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a standard MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn if it is determined that the risk-benefit ratio is no longer favorable.

The European Commission introduced legislative proposals in April 2023 intended to replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission provided the legislative proposals to the European Parliament and the European Council for their review and approval. In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the European Council adopted its position. A common position on the text was agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be formally adopted into EU law, and are not expected to become applicable before 2028.

Rest of the World Government Regulation

For other countries outside of Europe, such as some countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

M.D. Anderson License Agreement

In October 2021, we entered into the M.D. Anderson License Agreement with the Board of Regents of The University of Texas System, on behalf of M.D. Anderson. The entry into the M.D. Anderson License Agreement followed our exercise of rights granted to us under the parties' prior Collaborative Research & Option Agreement dated November 16, 2020, or the Collaboration Agreement, under which M.D. Anderson granted us an option to obtain a license to specified technologies. Under the M.D. Anderson License Agreement, M.D. Anderson granted to us (a) an exclusive, worldwide, sublicensable license under certain intellectual property arising under the Collaboration Agreement and certain patent rights, (b) a non-exclusive, worldwide, sublicensable license under certain other intellectual property and (c) a non-exclusive, worldwide, sublicensable license under additional intellectual property to practice certain intellectual property arising under the Collaboration Agreement, in each case (a)-(c), to make, have made, use, sell, offer for sale, import, develop, and commercialize certain products developed during the Collaboration Agreement, or the Developed Products, and licensed products for use in human therapeutics, diagnostics, and prophylactics.

Under the M.D. Anderson License Agreement, we are obligated to use commercially reasonable efforts to develop and seek marketing authorization for Developed Products and licensed products, and to commercialize such Developed Products and licensed products.

Under the M.D. Anderson License Agreement, we are obligated to pay to M.D. Anderson (a) a royalty on net sales of Developed Products and licensed products at a low single digit percentage, (b) milestone payments of up to $75.0 million upon the achievement of certain specified clinical and regulatory milestones and up to $90.0 million upon the achievement of certain specified sales milestone events, which milestones may be payable with respect to multiple products and indications and (c) a share of certain consideration received by us from sublicensees under any sublicense agreements with third parties.

As of December 31, 2025, we have made approximately $11.1 million in aggregate payments to M.D. Anderson in connection with the Collaboration Agreement and the M.D. Anderson License Agreement, including with respect to the payment of option exercise fees, milestone payments and certain reimbursable patent expenses and research fees which were incurred by M.D. Anderson prior to entering into the M.D. Anderson License Agreement.

The term of the M.D. Anderson License Agreement continues until the last to occur of: (a) the expiration of the last valid claim within certain licensed patent rights or (b) a specified period following the first commercial sale of a licensed product or Developed Product in any country.

We have the right to terminate the M.D. Anderson License Agreement for convenience upon certain prior written notice or by giving written notice to M.D. Anderson upon a material breach that is not remediated within a specified period of time. M.D. Anderson may terminate the M.D. Anderson License Agreement due to our insolvency or bankruptcy or by giving written notice to us upon a material breach that is not remediated within a

specified period of time. The M.D. Anderson License Agreement may be terminated by the Board of Regents upon notice for an uncured challenge of the Board of Regents' patents and by mutual agreement of us and the Board of Regents.

Employees and Human Capital Resources

As of June 30, 2026, we had 87 full-time employees; 29 of whom have M.D. or Ph.D. degrees. We also engage consultants and advisors with specialized expertise in clinical development, regulatory affairs, and other technical areas as needed to support our operations. Within our workforce, as of June 30, 2026, 68 employees are engaged in research and development and 19 are engaged in business development, finance, information technology, and general management and administration. Our human capital resources objectives include identifying, recruiting, engaging, incentivizing, developing, and retaining our existing and new employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our corporate headquarters is located in Cambridge, Massachusetts, where we lease and occupy 17,807 square feet of office and laboratory space. The current term of our Cambridge lease expires on January 31, 2027. In addition, our technical development facility is located in Bedford, Massachusetts, where we lease and occupy 9,896 square feet of office and laboratory space pursuant to a lease agreement that expires on December 31, 2028 with an option to extend the lease term for an additional five year period. We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

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 probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

The following table sets forth the name, age and position of the individuals who serve as our officers as of the date of this prospectus. The following also includes certain information regarding the individual experience, qualifications, attributes and skills of each individual as well as brief statements of those aspects of their backgrounds that led to conclusion that they are qualified to serve as a director. *Unless the context otherwise requires, references in this section to "we," "us," "our" and the "Company" refer to Obsidian Therapeutics, Inc. following the closing of the Mergers.*

Executive Officers And Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of August 15, 2026.

Name	Age	Position
Executive Officers:		
Madan Jagasia, M.D., M.S.	57	Chief Executive Officer and Director
Julie Feder	56	Chief Financial Officer
Parameswaran Hari, M.D., M.S.	58	Chief Medical Officer
Dana Alexander, M.B.A.	51	Chief Technical Officer
Non-Executive Directors:		
Maria Fardis, Ph.D., M.B.A.(1)(3)	58	Chairperson of the Board
Peter Barrett, Ph.D.(2)(3)	73	Director
Heidi Hagen, M.B.A.(1)(2)	57	Director
Matthew Norkunas, M.D., M.B.A.(3)	48	Director
Robert Ross, M.D.(1)(2)	53	Director

(1) Member of the compensation committee.
(2) Member of the nominating and corporate governance committee.
(3) Member of the audit committee.

Executive Officers

Madan Jagasia, M.D., M.S., has served as Legacy Obsidian's Chief Executive Officer and a member of the Board since January 2023. From August 2020 to January 2023, Dr. Jagasia served in various roles at Iovance Biotherapeutics, Inc. (Nasdaq: IOVA), or Iovance, a biopharmaceutical company, and most recently as Executive Vice President, Medical Affairs. Previously, Dr. Jagasia worked at Vanderbilt University Medical Center since 2001 in various roles and most recently as Chief Medical Officer and Executive Medical Director of the Vanderbilt-Ingram Cancer Center, or VICC, where he co-led the Translational Research and Interventional Oncology Research Program at VICC. Dr. Jagasia holds a M.B.B.S. from the GS Medical College & KEM Hospital and an M.S. and a Master of Management in Health Care Management from Vanderbilt University. We believe Dr. Jagasia is qualified to serve on the Board because of his scientific and professional background, and his familiarity with our company as Chief Executive Officer.

Julie Feder has served as Legacy Obsidian's Chief Financial Officer since January 2026. Previously, from August 2018 to October 2024, she served as Chief Financial Officer of Aura Biosciences, Inc. (Nasdaq: AURA), a biopharmaceutical company. Previously, Ms. Feder served as Chief Financial Officer at Verastem, Inc. (Nasdaq: VSTM), a biopharmaceutical company, from July 2017 to June 2018. Prior to joining Verastem, Ms. Feder served as the Chief Financial Officer at the Clinton Health Access Initiative, Inc. from September 2011 to July 2017. Ms. Feder began her career at Deloitte & Touche LLP, where she was senior manager of Audit, Consulting and Enterprise Risk Services. Ms. Feder holds a B.S. in Accounting from Yeshiva University's Sy Syms School of Business.

Parameswaran Hari, M.D., M.S., has served as Legacy Obsidian's Chief Medical Officer since January 2023. Previously, Dr. Hari served as Senior Vice President, Clinical Science at Iovance from November 2021 to January 2023. Prior to Iovance, Dr. Hari was the Chief of Hematology and Oncology at the Medical College of Wisconsin from March 2017 to November 2021. Dr. Hari also served the American Society of Transplantation and Cellular Therapy as its Secretary. Dr. Hari holds a M.B.B.S. from Kerala University, an M.D. from Central University of Pondicherry, and an M.S. from the Medical College of Wisconsin.

Dana Alexander, M.B.A., has served as Legacy Obsidian's Chief Technical Officer since April 2024. Previously, Mr. Alexander served as Senior Vice President of Technical Operations at AlloVir, Inc. (formerly Nasdaq: ALVR), a late-stage T cell therapy company, from September 2020 to April 2024. Prior to that, Mr. Alexander served as Vice President of Operations including Head of Business Operations, from January 2020 to September 2020 and Site General Manager, from January 2018 to January 2020 at Brammer Bio, now part of Thermo Fisher Scientific Inc. (NYSE: TMO). He also previously served as Chief Operations Officer at Anika Therapeutics, Inc. (Nasdaq: ANIK), a joint preservation company, and Senior Director of Manufacturing Operations at Genzyme, now part of Sanofi SA (Nasdaq: SNY), a global pharmaceutical company. Mr. Alexander holds a B.S. in Chemical Engineering from Northeastern University and an M.B.A. from Boston University.

Non-Executive Directors

Maria Fardis, Ph.D., M.B.A., is chairperson of the Obsidian Board and has served as a member of the Obsidian Board since October 2021. Dr. Fardis has served as the Chief Executive Officer of AirNexus Therapeutics, a biotechnology company, since January 2026, and as a Venture Partner at Frazier Life Sciences Management, L.P., or Frazier, a healthcare investment firm, since September 2021. Dr. Fardis served as the Chief Executive Officer of Lassen Therapeutics, a biotechnology company, from April 2021 to November 2025 and as a member of its board of directors from April 2021 to July 2026. Dr. Fardis previously served as President and Chief Executive Officer of Iovance and as a member of its board of directors from June 2016 through June 2021. Dr. Fardis previously served as the Chief Operating Officer of Acerta Pharma B.V., a biopharmaceutical company, from January 2015 to March 2016. From April 2011 to December 2014, she worked at Pharmacyclics, Inc. (formerly Nasdaq: PCYC; acquired by AbbVie Inc.) in various roles and most recently served as Chief of Oncology Operations and Alliances. Prior to that, from 2001 to 2011, Dr. Fardis held increasingly senior positions in medicinal chemistry and project and portfolio management at Gilead Sciences, Inc. (Nasdaq: GILD). Dr. Fardis has served on the board of directors of CRISPR Therapeutics AG (Nasdaq: CRSP), a biopharmaceutical company, since June 2022. Dr. Fardis holds a B.S. in chemistry from the University of Illinois, Urbana-Champaign, a Ph.D. in Organic Chemistry from the University of California, Berkeley, and an M.B.A. from Golden Gate University. We believe Dr. Fardis is qualified to serve on the Board because of her experience as an executive in the life sciences industry, extensive experience in drug development, and strong scientific background.

Peter Barrett, Ph.D., has served as a member of the Obsidian Board since September 2015. Dr. Barrett was formerly a partner at Atlas Venture, an early-stage life sciences venture capital fund, where he was involved in the creation of several therapeutic and drug discovery platform companies. Previously, he was a co-founder, Executive Vice President and Chief Business Officer of Celera Genomics. Dr. Barrett has served as the Chairman of Synlogic, Inc. (Nasdaq: SYBX), a biotechnology company, since 2017 and on the board of directors of Revvity, Inc. (NYSE: RVTY), a life sciences and diagnostics company, since 2012. Dr. Barrett is also on the Advisory Council of the Blavatnik Fellowship program. Dr. Barrett previously served on the board of Larimar Therapeutics, Inc. (Nasdaq: LRMR), a biotechnology company, until 2023, and previously served on the board of Cadent Therapeutics (acquired by Novartis AG), Vitae Pharmaceuticals, Inc. (formerly Nasdaq: VTAE; acquired by Allergan PLC), Stromedix, Inc. (acquired by Biogen Idec), NovaMed Pharmaceuticals, Inc. (acquired by SciClone Pharmaceuticals, Inc.), Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), Harbour Antibodies BV (acquired by Harbour BioMed), Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA), Sirion Therapeutics, Inc. (acquired by Alcon Inc. and Bausch + Lomb Corporation), and Archemix (acquired by Baxter International Inc.). In addition, Dr. Barrett is a board member of Nucleate, a student run non-profit organization representing the global community of bio-innovators. Dr. Barrett holds a B.S. in chemistry from Lowell Technological Institute (now known as the University of Massachusetts, Lowell) and a Ph.D. in analytical chemistry

from Northeastern University. We believe Dr. Barrett is qualified to serve on the Board because of his extensive experience in the life sciences industry.

Heidi Hagen, M.B.A., has served as a member of Obsidian's Board since November 2021. Ms. Hagen has over 35 years of experience in the Biotechnology Industry primarily as an operations executive. Ms. Hagen has served as a member of the board of directors of Vericel Corporation (Nasdaq: VCEL; formerly known as Aastrom Biosciences, Inc.), a biopharmaceutical company, since August 2013. Ms. Hagen also serves as a member of the board of directors of Dimension Bio, Applied StemCell, Inc., and A-Alpha Bio, Inc. She previously served as the Chief Technical Officer of Sonoma Biotherapeutics, Inc., a biotechnology company, from November 2021 to June 2023. Prior to that, Ms. Hagen served as the Interim Chief Executive Officer and member of the board of directors of Ziopharm Oncology, Inc. (formerly Nasdaq: ZIOP; now Alaunos Therapeutics, Inc.), a biopharmaceutical company, from 2019 to 2021. Ms. Hagen also co-founded Vineti, Inc., a software platform company for cell and gene therapy supply chain management, where she served as Advisor and Chief Strategy Officer from 2015 to 2021. Prior to those experiences, Ms. Hagen was Senior Vice President of Operations at Dendreon (2002 to 2012) where she oversaw the commercialization of the first active cellular therapy, Provenge. And, she held various operational and project management roles at Immunex Corporation from 1993 to 2002. Ms. Hagen holds a B.S. in cell biology, an M.S. in bioengineering, and an M.B.A. from the University of Washington. We believe Ms. Hagen is qualified to serve on the Board because of her significant leadership experience in the biopharmaceutical industry.

Matthew Norkunas, M.D., M.B.A., has served as a member of the Obsidian Board since April 2023. From January 2025 to August 2026, Dr. Norkunas served as the Chief Financial Officer and President of Tubulis, Inc. (acquired by Gilead Sciences, Inc.), a biotechnology company. From July 2020 to January 2025, Dr. Norkunas served as the Chief Financial Officer of Generation Bio Co. (formerly Nasdaq: GBIO; acquired by XOMA Royalty Corporation), a genetics medicine company. Previously, Dr. Norkunas served as the Chief Financial Officer and Head of Corporate and Business Development at SomaLogic, Inc. (acquired by Illumina, Inc.), a protein biomarker discovery and clinical diagnostics company, from February 2016 to June 2020. From July 2012 to January 2016, Dr. Norkunas served as a senior equity analyst at Marsico Capital Management, LLC, an investment company, where he served as the firm's primary health care investment specialist. Dr. Norkunas began his career as a practicing anesthesiologist. Dr. Norkunas holds a B.A. from St. Mary's College of Maryland, an M.D. from University of Maryland School of Medicine, and an M.B.A. from Columbia Business School. We believe Dr. Norkunas is qualified to serve on the Board because of his significant financial experience of biotechnology companies and clinical background.

Robert Ross, M.D., has served as a member of the Obsidian Board since September 2020. Since November 2023, Dr. Ross has served as the Chief Executive Officer of Clasp Therapeutics, Inc., a pharmaceutical company. Prior to that, Dr. Ross served as the Chief Executive Officer and a member of board of directors of Surface Oncology, Inc. (formerly Nasdaq: SURF; acquired by Coherus BioSciences, Inc.), an immuno-oncology company, from April 2021 until July 2023 and had previously served as the Chief Medical Officer from October 2016 to March 2021. Dr. Ross served as Head of Oncology at bluebird bio, Inc. (formerly Nasdaq: BLUE; now Genetix Biotherapeutics, Inc.) from October 2015 to October 2016, Senior Vice President of Clinical Development and Pharmacovigilance from January 2015 to October 2016, and Vice President of Clinical Development from October 2012 to January 2015. Prior to that, he worked at Infinity Pharmaceuticals, Inc. from October 2007 to October 2012. Dr. Ross was a Fellow in Medical Oncology and a faculty member at the Dana Farber Cancer Institute from July 2003 to August 2007, and then maintained a clinical practice at Dana Farber Cancer Institute from August 2007 to October 2015. Dr. Ross has served on the board of directors of Xilio Therapeutics, Inc. (Nasdaq: XLO), a biotechnology company, since June 2022. Dr. Ross holds a B.S. in Biological Sciences and a B.A. in Philosophy from Stanford University, an M.S. in Medical Science as part of the Clinical Investigator Training Program from Harvard Medical School, and an M.D. from Columbia University College of Physicians and Surgeons. He completed his residency training in Internal Medicine at the University of California, San Francisco. We believe that Dr. Ross is qualified to serve on the Board because of his extensive executive experience in the life science industry and clinical background.

EXECUTIVE AND DIRECTOR COMPENSATION

Unless the context otherwise requires, references in this section to "Parent," "we," "us," "our," and the "Company" refer to Obsidian Therapeutics, Inc. (formerly Gazelle Parent, Inc.). Obsidian Therapeutics, Inc. (formerly Gazelle Parent, Inc.) was incorporated on April 14, 2026 and therefore did not have any executive officers or pay any executive compensation during the fiscal year ended December 31, 2025. Accordingly, the historical executive compensation disclosure below relates to the executive officers of Legacy Obsidian who served as executive officers of Legacy Obsidian during fiscal year 2025.

The following discussion contains forward looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Please see the section titled "*Special Note Regarding Forward-Looking Statements*."

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to "emerging growth companies" as such term is defined in the rules promulgated under the Securities Act. The compensation provided to our named executive officers for the fiscal year ended December 31, 2025, or Fiscal Year 2025, is detailed in the 2025 Summary Compensation Table below and accompanying footnotes and narrative that follow.

Legacy Obsidian's executive officers who served as executive officers during Fiscal Year 2025 are:

- Madan Jagasia, M.D., M.S., Legacy Obsidian's Chief Executive Officer;
- Dana Alexander, Legacy Obsidian's Chief Technical Officer; and
- Parameswaran Hari, M.D., M.S., Legacy Obsidian's Chief Medical Officer.

We refer to these executive officers as Legacy Obsidian's named executive officers.

To date, the compensation of Legacy Obsidian's named executive officers has primarily consisted of a combination of base salary, annual cash incentive compensation, and long-term incentive compensation, as described in more detail below. Legacy Obsidian's executive officers, like all full-time employees, are eligible to participate in Legacy Obsidian's health, welfare, and retirement benefit plans.

2025 Summary Compensation Table

The following table shows the total compensation earned by, or paid to, Legacy Obsidian's named executive officers for services rendered to Legacy Obsidian in all capacities during Fiscal Year 2025:

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Madan Jagasia, M.D., M.S. *Chief Executive Officer*	2025	559,728	195,905	500,137	—	60,000(3)	1,315,770
Dana Alexander, M.B.A., *Chief Technical Officer*	2025	434,700	106,502	148,795	—	—	689,997
Parameswaran Hari, M.D., M.S. *Chief Medical Officer*	2025	484,380	118,673	120,898	—	—	723,951

(1) The amount reported represents a discretionary annual cash bonus earned by the applicable named executive officer for performance in the applicable fiscal year and paid in the next fiscal year. For more information on these bonuses, see the description of Fiscal Year 2025 annual cash bonuses below.

(2) The amount reported represents the aggregate incremental fair value related to the repricing, in Fiscal Year 2025, of certain stock option awards held by the applicable named executive officer that were granted prior to Fiscal Year 2025, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or FASB ASC Topic 718. The assumptions used in calculating the incremental fair values include a common stock fair value of $0.78, a risk-free interest rate ranging from 4.07% to 4.14%, an expected dividend yield of 0.00%, an expected term of 3.9 to 5.2 years, and an expected volatility ranging from 76.67% to 77.45%. The amount reported reflects the accounting cost for the repricing of certain option awards and do not correspond to the actual economic value that may be received by the named executive officer upon the exercise of the option awards or any sale of the underlying securities.

(3) The amount reported represents a travel stipend of $5,000 per month for Dr. Jagasia for travel between his home in Tennessee and our offices in Massachusetts, inclusive of certain housing costs, which was payable pursuant to the terms of his offer letter with Legacy Obsidian.

Narrative Disclosure to the 2025 Summary Compensation Table

2025 Base Salaries

During Fiscal Year 2025, Dr. Jagasia, Mr. Alexander, and Dr. Hari each received a base salary to compensate them for services rendered to us. Base salaries are intended to provide a fixed cash component of compensation reflecting the executive's skill set, experience, role, and responsibilities. Base salaries are expected to be reviewed periodically and approved by the compensation committee of the Legacy Obsidian Board or Legacy Obsidian Board following recommendation by its compensation committee, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience, as well as changes in the business.

Fiscal Year 2025 base salaries for each of Legacy Obsidian's named executive officers are set forth in the table below:

Name	Annual Base Salary ($)
Madan Jagasia, M.D., M.S.	559,728
Dana Alexander, M.B.A.	434,700
Parameswaran Hari, M.D., M.S.	484,380

2025 Annual Cash Bonuses

For Fiscal Year 2025, each of the named executive officers was eligible to earn an annual cash bonus based on the Company's achievement of certain corporate performance milestones. The target annual bonus for each of Legacy Obsidian's named executive officers for Fiscal Year 2025 was equal to the percentage of the executive's respective annual base salary specified below:

Name	Target Annual Bonus
Madan Jagasia, M.D., M.S.	50%
Dana Alexander, M.B.A.	35%
Parameswaran Hari, M.D., M.S.	35%

Pursuant to Legacy Obsidian's bonus program, each named executive officer's annual cash bonus is typically determined by reference to the Company's achievement of pre-determined clinical, financial and organizational, and pipeline goals. During Fiscal Year 2025, Legacy Obsidian made several strategic changes to our business and as a result, Legacy Obsidian's Board determined that not all of the pre-determined corporate goals for Fiscal Year 2025 were applicable following such changes. However, in light of the continued progress toward certain corporate goals, Legacy Obsidian's Board approved discretionary annual cash bonuses for the named executive officers equal to 70% of their applicable annual bonus targets. The annual cash bonus paid to each of Legacy

Obsidian's named executive officers for Fiscal Year 2025 is set forth in the "*Bonus*" column of the "*2025 Summary Compensation Table*" above.

Equity Incentive Compensation

Legacy Obsidian believes equity grants provide its executives with a strong link to its long-term performance, create an ownership culture, and help to align the interests of its executives and stockholders. In addition, Legacy Obsidian believes equity grants promote executive retention because they encourage its executive officers to remain in its service during the vesting period. During Fiscal Year 2025, Legacy Obsidian did not grant any equity incentive awards to its executive officers. However, for retention and motivational purposes, during Fiscal Year 2025, Legacy Obsidian repriced certain options to purchase shares of its common stock that were previously granted to its employees and other service providers, including its named executive officers, to lower the exercise price of such options to the then-current fair market value of its common stock. For additional information regarding outstanding equity awards held by its named executive officers as of December 31, 2025, see the "*Outstanding Equity Awards at 2025 Fiscal Year End*" table below.

401(k) Plan and Health and Welfare Benefits

Legacy Obsidian currently maintains a tax-qualified 401(k) retirement savings plan, or the 401(k) Plan, for its employees, including its named executive officers, who satisfy certain eligibility requirements. Legacy Obsidian's named executive officers are eligible to participate in the 401(k) Plan on the same terms as other full-time employees; provided, however, that employees with the title of Vice President or higher, including its named executive officers, were not permitted to receive matching or non-elective contributions under the 401(k) Plan during Fiscal Year 2025. Beginning in calendar year 2026, employees with the title of Vice President or Senior Vice President, but not executive officers, are eligible to receive matching and non-elective contributions under the 401(k) Plan on the same terms as other full-time employees. Legacy Obsidian's 401(k) Plan is intended to qualify for favorable tax treatment under Section 401(a) of the Code and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. Legacy Obsidian believes that providing a vehicle for tax-deferred retirement savings through our 401(k) Plan adds to the overall desirability of its executive compensation package and further incentivizes its employees, including its named executive officers, in accordance with its compensation policies. Other than the 401(k) Plan, it does not provide any qualified or non-qualified retirement or deferred compensation benefits to its employees, including its named executive officers.

All of Legacy Obsidian's full-time employees, including its named executive officers, are eligible to participate in its health and welfare plans.

Perquisites/Personal Benefits

Perquisites or other personal benefits are not a significant component of Legacy Obsidian's executive compensation program. Accordingly, it does not provide significant perquisites or other personal benefits to its executive officers, including its named executive officers, except for stipends for travel and housing costs for Dr. Jagasia, as described in the "*2025 Summary Compensation Table*" above.

Employment Arrangements with Named Executive Officers

Employment Arrangements in Effect Prior to the Closing of the Mergers

Legacy Obsidian entered into offer letters with each of its named executive officers in connection with their commencement of employment, which set forth the terms and conditions of their employment, including initial base salary, initial target annual cash incentive compensation opportunity, initial equity awards, and eligibility to participate in Legacy Obsidian's employee benefit plans generally offered to Legacy Obsidian's employees.

Legacy Obsidian also entered into a Severance and Change in Control Agreement with each of its named executive officers that provide for specified payments and benefits in connection with a termination of employment in certain circumstances. Legacy Obsidian's goal in providing these severance and change in control benefits is to offer sufficient cash continuity protection such that the named executive officers will focus their full time and attention on the requirements of the business rather than the potential implications of a qualifying employment termination or change in control for their respective positions. Legacy Obsidian prefers to have certainty regarding the potential severance amounts payable to its named executive officer, rather than negotiate severance at the time that a named executive officer's employment terminates.

The material terms of the offer letters and Severance and Change in Control Agreements with the named executive officers are summarized below.

Madan Jagasia, M.D., M.S. Offer Letter

On January 4, 2023, Legacy Obsidian entered into an offer letter with Dr. Jagasia for the position of Chief Executive Officer, or the Jagasia Offer Letter, which provided for Dr. Jagasia's at-will employment. Pursuant to the Jagasia Offer Letter, Dr. Jagasia was eligible to receive an annual base salary, subject to periodic review and adjustment at our discretion and an annual cash incentive bonus, as determined by Legacy Obsidian's Board. In addition, Dr. Jagasia receives a monthly stipend of $5,000 for travel between his home in Tennessee and our offices in Massachusetts and is eligible to participate in the employee benefit plans generally available to Legacy Obsidian's employees, subject to the terms of those plans.

Dana Alexander, M.B.A. Offer Letter

On April 21, 2024, Legacy Obsidian entered into an offer letter with Mr. Alexander for the position of Chief Technical Officer, or the Alexander Offer Letter, which provided for Mr. Alexander's at-will employment. Pursuant to the Alexander Offer Letter, Mr. Alexander was eligible to receive an annual base salary, subject to periodic review and adjustment at our discretion and an annual cash incentive bonus, as determined by the Legacy Obsidian Board. In addition, Mr. Alexander is eligible to participate in the employee benefit plans generally available to Legacy Obsidian's employees, subject to the terms of those plans.

Parameswaran Hari, M.D., M.S. Offer Letter

On January 7, 2023, Legacy Obsidian entered into an offer letter with Dr. Hari for the position of Chief Development Officer, or the Hari Offer Letter, which provided for Dr. Hari's at-will employment. Pursuant to the Hari Offer Letter, Dr. Hari was eligible to receive an annual base salary, subject to periodic review and adjustment at our discretion and an annual cash incentive bonus, as determined by Legacy Obsidian's Board. In addition, Dr. Hari is eligible to participate in the employee benefit plans generally available to Legacy Obsidian's employees, subject to the terms of those plans.

Severance and Change in Control Agreements

Pursuant to the Severance and Change in Control Agreements entered into with the named executive officers, in the event that a named executive officer's employment was terminated by Legacy Obsidian for any reason other than Cause (as defined in the Severance and Change in Control Agreements), death or disability or by the named executive officer for Good Reason (as defined in the Severance and Change in Control Agreements), subject to the named executive officer's execution, and the effectiveness, of a separation agreement, including a general release of claims in favor of Legacy Obsidian and its affiliates, the named executive officers were entitled to receive (i) (A) for Dr. Jagasia, an amount equal to 12 months of his current base salary, any earned but unpaid bonus for the fiscal year prior to the date of termination, and a pro-rated target bonus for the fiscal year of termination and (B) for Mr. Alexander and Dr. Hari, six months of his then-current base salary and (ii) if the named executive officer was participating in Legacy Obsidian's group health plan immediately prior to the date

of termination and elected COBRA health continuation, a monthly cash payment for six months (or, in the case of Dr. Jagasia, 12 months) in an amount equal to the monthly employer contribution we would have made to provide health insurance to the named executive officer and his eligible dependents if he had remained employed by Legacy Obsidian.

In addition, in lieu of the payments and benefits described above, in the event that a named executive officer's employment was terminated by Legacy Obsidian for any reason other than Cause, death or disability or a by the named executive officer for Good Reason, in each case, immediately before, on, or within the 12 months immediately after a Change in Control (as defined in the Severance and Change in Control Agreements), subject to the named executive officer's execution, and the effectiveness, of a separation agreement, including a general release of claims in favor of Legacy Obsidian and its affiliates, named executive officers were entitled to receive (i) (A) for Dr. Jagasia, an amount equal to 12 months of his current base salary plus his target annual bonus and any earned but unpaid bonus for the fiscal year prior to the date of termination and (B) for Mr. Alexander and Dr. Hari, an amount equal to nine months of his current base salary plus his target annual bonus and any earned but unpaid bonus for the fiscal year prior to the date of termination, (ii) if the named executive officer was participating in Legacy Obsidian's group health plan immediately prior to the date of termination and elected COBRA health continuation, a monthly cash payment for nine months (or, in the case of Dr. Jagasia, 12 months) in an amount equal to the monthly employer contribution Legacy Obsidian would have made to provide health insurance to the named executive officer and his eligible dependents if he had remained employed by Legacy Obsidian and (iii) full acceleration of vesting of all stock options and other stock-based awards subject solely to time-based vesting held by the named executive officer and, for Dr. Jagasia, extension of the post-termination exercise period for his stock options until the earlier of six months following the date of termination and the original expiration date of the stock option.

The payments and benefits provided under the Severance and Change in Control Agreements in connection with a change in control may not have been eligible for a federal income tax deduction by Legacy Obsidian pursuant to Section 280G of the Code. These payments and benefits could have also subjected the named executive officers to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then pursuant to each of the Severance and Change in Control Agreements, those payments or benefits would have been reduced, but only if such reduction would result in the named executive officer retaining a larger portion of such payments and benefits on an after-tax basis than if no reduction was made and the excises taxes had been paid.

Employment Arrangements in Effect Following the Closing of the Mergers

We entered into executive employment agreements with each of its named executive officers in connection with the Mergers that superseded the offer letters and adopted an Executive Severance Plan that superseded the Severance and Change in Control Agreements. The material terms of the executive employment agreements with the named executive officers and the Executive Severance Plan are summarized below.

Madan Jagasia, M.D., M.S. Executive Employment Agreement

We entered into an executive employment agreement with Dr. Jagasia for the position of Chief Executive Officer, or the Jagasia Employment Agreement, which superseded the Jagasia Offer Letter and became effective as of the closing of the Mergers. Pursuant to the Jagasia Employment Agreement, Dr. Jagasia is eligible to receive an annual base salary of $638,200, subject to annual review and adjustment at our discretion and an annual cash incentive bonus, as determined by our Board, which bonus has a target of 55% of Dr. Jagasia's base salary. Dr. Jagasia is eligible to participate in the employee benefit plans generally available to employees, subject to the terms of those plans, and Severance Plan (as defined below) as a Tier 1 Executive, as defined in the Severance Plan.

Dana Alexander, M.B.A. Executive Employment Agreement

We entered into an executive employment agreement with Mr. Alexander for the position of Chief Technical Officer, or the Alexander Employment Agreement, which superseded the Alexander Offer Letter and became effective as of the closing of the Mergers. Pursuant to the Alexander Employment Agreement, Mr. Alexander is eligible to receive an annual base salary of $461,480, subject to annual review and adjustment at our discretion and an annual cash incentive bonus, as determined by our Board, which bonus has a target of 40% of Mr. Alexander's base salary. Mr. Alexander is eligible to participate in the employee benefit plans generally available to employees, subject to the terms of those plans, and the Severance Plan as a Tier 2 Executive, as defined in the Severance Plan.

Parameswaran Hari, M.D., M.S. Executive Employment Agreement

We entered into an executive employment agreement with Dr. Hari for the position of Chief Medical Officer, or the Hari Employment Agreement, which superseded the Hari Offer Letter and became effective as of the closing of the Mergers. Pursuant to the Hari Employment Agreement, Dr. Hari is eligible to receive an annual base salary of $538,167, subject to annual review and adjustment at our discretion and an annual cash incentive bonus, as determined by our Board, which bonus has a target of 40% of Dr. Hari's base salary. Dr. Hari is eligible to participate in the employee benefit plans generally available to employees, subject to the terms of those plans, and the Severance Plan as a Tier 2 Executive, as defined in the Severance Plan.

Executive Severance Plan

In connection with the Mergers, Parent adopted an Executive Severance Plan, or the Severance Plan, that became effective as of the closing of the Mergers, in which the named executive officers and certain other employees are eligible to participate.

The Severance Plan provides that upon a (i) termination of a named executive officer's employment by Parent for any reason other than due to Cause, death, or Disability or (ii) a named executive officer's resignation for Good Reason (each as defined in the Severance Plan), in each case outside of the period beginning three months prior to and ending on the one-year anniversary of a Change in Control (as defined in the Severance Plan), or such period, the Change in Control Period, each named executive officer is entitled to receive, subject to the execution and delivery of an effective and irrevocable separation agreement containing, among other things, a general release of claims in Parent's favor and continued compliance with all applicable continuing obligations: (A) continued payment of the named executive officer's base salary for 12 months following termination, such period, the Severance Period, and, for the Chief Executive Officer, a pro-rated target bonus and any earned but unpaid annual incentive compensation for the prior year; and (B) an amount equal to the employer portion of the monthly COBRA premium until the earliest of (x) the end of the Severance Period, (y) the date the named executive officer becomes eligible for group medical plan benefits under any other employer's group medical plan, or (z) the cessation of the named executive officer's health continuation rights under COBRA.

The Severance Plan also provides that upon a (i) termination of a named executive officer's employment by Parent other than for Cause or due to death or Disability or (ii) resignation by a named executive officer for Good Reason, in each case within the Change in Control Period, each named executive officer is entitled to receive, in lieu of the payments and benefits above and subject to the execution and delivery of an effective and irrevocable separation agreement containing, among other things, a general release of claims in Parent's favor and continued compliance with all applicable continuing obligations: (A) a lump sum amount equal to one times (or, in the case of the Chief Executive Officer, one and a half times) the sum of the named executive officer's base salary and target annual bonus in effect immediately prior to the date of termination or immediately prior to the change in control, if higher; (B) any earned but unpaid annual incentive compensation for the prior year; (C) an amount equal to the employer portion of the monthly COBRA premium until the earliest of (x) 12 months (or, in the case of the Chief Executive Officer, 18 months) following termination of employment, (y) the date the named

executive officer becomes eligible for group medical plan benefits under any other employer's group medical plan, or (z) the cessation of the named executive officer's health continuation rights under COBRA; and (D) accelerated vesting of all outstanding and unvested equity awards held by the named executive officer that are subject solely to time-based vesting and, for the Chief Executive Officer, all vested stock options will remain exercisable until the earlier of six months following the date of termination and the original expiration date of the stock option.

Pursuant to Section 280G of the Code, Parent may not be eligible for a U.S. federal income tax deduction on the payments and benefits provided under the Severance Plan in connection with a Change in Control. These payments and benefits may also subject an eligible participant, including the named executive officers, to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a Change in Control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the eligible participant.

Outstanding Equity Awards at 2025 Fiscal Year End

The following table sets forth information concerning outstanding equity awards held by Legacy Obsidian's named executive officers as of December 31, 2025.

		Option Awards(1)					
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)(2)	Option Expiration Date
Madan Jagasia, M.D., M.S.	6/25/2024	6/25/2024	1,557,750	2,596,250(3)	—	0.78	6/24/2034
	2/28/2023	1/30/2023	4,868,516	2,212,962(4)	—	0.78	2/27/2033
	2/28/2023	9/13/2023	55,324	—	—	0.78	2/27/2033
	2/28/2023	—	110,648	—	—	0.78	2/27/2033
	2/28/2023	1/3/2024	103,732	6,916(5)	—	0.78	2/27/2033
	2/28/2023	1/12/2024	48,408	6,916(7)	—	0.78	2/27/2033
	2/28/2023	—	442,592	—	—	0.78	2/27/2033
Dana Alexander, M.B.A.	6/25/2024	4/29/2024	372,375	620,625(6)	—	0.78	6/24/2034
	5/15/2024	4/29/2024	630,694	1,051,157(4)	177,037(8)	0.78	5/14/2034
Parameswaran Hari, M.D., M.S.	6/25/2024	6/25/2024	353,812	589,688(3)	—	0.78	6/24/2034
	2/28/2023	1/17/2023	1,217,128	553,241(4)	—	0.78	2/27/2033
	2/28/2023	9/13/2023	48,685	—	—	0.78	2/27/2033
	2/28/2023	1/3/2024	91,284	6,086(5)	—	0.78	2/27/2033
	2/28/2023	—	97,370	—	—	0.78	2/27/2033
	2/28/2023	1/12/2024	42,599	6,086(7)	—	0.78	2/27/2033

(1) All awards were granted under Legacy Obsidian's 2016 Stock Option and Grant Plan and are subject to certain acceleration of vesting rights as set forth in the applicable named executive officer's Severance and Change in Control Agreement, as described above.
(2) Options were repriced to $0.78 per share in June 2025.
(3) This award vests in equal quarterly installments over four years from the Vesting Commencement Date, subject to the grantee's continued service through the applicable vesting date.
(4) This award vested 25% on the first anniversary of the Vesting Commencement Date, with the remainder vesting in equal quarterly installments over the following three years, subject to the grantee's continued service through the applicable vesting date.
(5) This award vested 50% on the Vesting Commencement Date, with the remainder vesting in equal quarterly installments over the following two years, subject to the grantee's continued service through the applicable vesting date.
(6) 19% of the award vested on April 29, 2025 and the remainder vests in equal 1/16th installments on each June 25th, September 25th, December 25th and March 25th thereafter, through the four-year anniversary of the grant date, subject to the grantee's continued service through the applicable vesting date.
(7) This award vests in equal quarterly installments over two years from the Vesting Commencement Date, subject to the grantee's continued service through the applicable vesting date.
(8) This award vests 50% upon the achievement of certain corporate performance goals, and 50% in equal quarterly installments over the two years thereafter, subject to the grantee's continued service through the applicable vesting dates.

Employee Benefit and Equity Compensation Plans

2016 Stock Option and Grant Plan

The 2016 Stock Option and Grant Plan, or 2016 Plan, was initially adopted by the Legacy Obsidian Board and approved by Legacy Obsidian's stockholders on March 23, 2016, and most recently amended in March 2024 to increase the number of shares reserved for issuance thereunder. The 2016 Plan expired in March 2026. Under the 2016 Plan, as amended, Legacy Obsidian reserved for issuance an aggregate of 48,749,161 shares of Legacy Obsidian common stock. The maximum number of shares that could have been issued pursuant to incentive stock options under the 2016 Plan was 48,749,161 shares. These numbers were subject to adjustment in the event of a reorganization, stock split, reverse stock split, stock dividend, recapitalization, reclassification, or other similar change in capitalization or event. As of December 31, 2025, options to purchase 38,061,610 shares of Legacy Obsidian's common stock were outstanding under the 2016 Plan. Legacy Obsidian's Board determined not to make any further awards under the 2016 Plan following the closing of the Mergers and the PIPE Financing all outstanding awards under the 2016 Plan will continue to be governed by their existing terms. In connection with the Mergers, we adopted a new incentive equity plan under which we will grant equity-based awards following the Mergers and the PIPE Financing, as described under "*—2026 Equity Incentive Plan*" below. The following summary describes the material terms of the 2016 Plan. This summary is not a complete description of all provisions of the 2016 Plan and is qualified in its entirety by reference to the 2016 Plan.

The shares of Legacy Obsidian common stock underlying any awards that are forfeited, cancelled, reacquired by us prior to vesting, satisfied without the issuance of Legacy Obsidian common stock, or otherwise terminated (other than by exercise) and shares that are withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding under the 2016 Plan were previously added back to the shares of Legacy Obsidian common stock available for issuance under our 2016 Plan (and, following the completion of the Mergers and the PIPE Financing, are added back to the shares of our common stock available for issuance under the 2026 Equity Plan, or 2026 Plan).

The Legacy Obsidian Board acted as administrator of the 2016 Plan. The administrator had full power to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be granted, make any combination of awards to participants, determine the specific terms and conditions of each award, and accelerate at any time the exercisability or vesting of any award, subject to the provisions of the 2016 Plan. Persons eligible to participate in Legacy Obsidian's 2016 Plan were Legacy Obsidian's full or part-time officers, employees, directors, consultants, and other key persons as selected from time to time by the administrator in its discretion.

The 2016 Plan permitted the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (2) options that do not so qualify. The option exercise price of each option was determined by the administrator but could not be less than 100% of the fair market value of the common stock on the date of grant or, in the case of an incentive stock option granted to a 10% owner, the exercise price could not be less than 110% of the fair market value of Legacy Obsidian common stock on the date of grant. The term of each option was fixed by the administrator and could not exceed ten years from the date of grant (or five years in the case of certain incentive stock option grants). The administrator determined at what time or times each option may be exercised.

The administrator of the 2016 Plan could have awarded restricted shares of Legacy Obsidian common stock and restricted stock units subject to such conditions and restrictions as it determined. These conditions and restrictions could have included continued employment or other service relationship through a specified vesting period and/or the achievement of certain performance goals.

The administrator of the 2016 Plan could also have granted shares of common stock that were free from any restrictions under the 2016 Plan. Unrestricted stock could have been granted to participants in recognition of past services or for other valid consideration and could have been issued in lieu of cash compensation due to such participant.

In the event of certain corporate transactions and events, including a reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split, or other similar change to capital stock, the administrator of the 2016 Plan is required to make appropriate adjustments to the maximum number of shares reserved for issuance under the 2016 Plan, the number and kind of securities subject to outstanding awards under the 2016 Plan, and the repurchase or exercise price of any outstanding awards under the 2016 Plan.

The 2016 Plan provides that upon the effective time of a Sale Event (as defined in the 2016 Plan), the 2016 Plan and all outstanding stock options under the 2016 Plan will terminate, unless assumed or continued by the successor entity. In the event of such termination, optionees will be provided an opportunity to exercise options that were then exercisable or would become exercisable as of the effective time of the Sale Event within a specified period of time prior to the consummation of the Sale Event. In addition, Legacy Obsidian had the right to provide for cash payment to holders of options, in exchange for the cancellation thereof, in an amount equal to the difference between the value of the consideration payable per share of Legacy Obsidian common stock in the Sale Event and the per share exercise price of such options, multiplied by the number of shares subject to such option to the extent then vested and exercisable. In the event of a Sale Event, unvested restricted stock and restricted stock units (other than those becoming vested as a result of the Sale Event) will be forfeited unless such awards were assumed or continued by the successor entity. If shares of restricted stock are forfeited in connection with a Sale Event, those shares of restricted stock may be repurchased at a price per share equal to the original per share purchase price of such shares. Legacy Obsidian had the right to provide for cash payment to holders of restricted stock or restricted stock units, in exchange for the cancellation thereof, in an amount per share equal to the value of the consideration payable per share of common stock in the Sale Event.

Legacy Obsidian's Board had authority to amend or discontinue the 2016 Plan at any time, subject to stockholder approval where required by applicable law. The administrator of the 2016 Plan is authorized to amend or cancel any outstanding award for purposes of satisfying changes in law or for any other lawful purpose, provided that no such action would adversely affect rights under an outstanding award without the holder's consent. The administrator of the 2016 Plan is authorized to exercise its discretion to reduce the exercise price of outstanding stock options or effect the repricing of such awards through cancellation and re-grants.

The 2016 Plan expired in March 2026. As described above, the Legacy Obsidian Board has determined not to make any further awards under our 2016 Plan following the completion of the Mergers.

2026 Equity Incentive Plan

The 2026 Plan was adopted by the Parent Board and approved by Parent's sole stockholder on June 30, 2026, and became effective immediately preceding the closing of the Mergers. The 2026 Plan replaced the 2016 Plan. The 2026 Plan allows Obsidian to make equity-based and cash-based incentive awards to our officers, employees, directors, and consultants. The following summary describes the material terms of the 2026 Plan. This summary is not a complete description of all provisions of the 2026 Plan and is qualified in its entirety by reference to the 2026 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Authorized Shares. We have reserved 7,494,541 shares of our common stock for issuance under the 2026 Plan, or the Initial Limit. The 2026 Plan provides that the number of shares reserved and available for issuance under the 2026 Plan will automatically increase on January 1, 2027 and each January thereafter during the term of the 2026 Plan, by (i) 5% of the sum of (A) the number of shares of our common stock issued and outstanding on the immediately preceding December 31, (B) the number of shares of our preferred stock issued and outstanding on the immediately preceding December 31 and (C) the number of shares of our stock issuable pursuant to the exercise of any outstanding, pre-funded warrants to acquire our common stock or preferred stock on the date immediately preceding December 31, or the Outstanding Shares, or (ii) such lesser number of shares as determined by our compensation committee, or the Annual Increase. The number of shares of our common stock reserved for issuance under the 2026 Plan will be subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

The shares we issue under the 2026 Plan will be authorized but unissued shares or shares that we reacquire. The shares of our common stock underlying any awards under the 2026 Plan and the 2016 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) are added back to the shares of common stock available for issuance under the 2026 Plan. The maximum number of shares of our common stock that may be issued pursuant to incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2027 and on each January 1 thereafter by the lesser of the Annual Increase for such year or the Initial Limit.

Non-Employee Director Limit. The grant date fair value of all awards under the 2026 Plan and all other cash compensation paid by us to any non-employee director during any one calendar year for services as a non-employee director may not exceed $750,000; provided, however, that such amount shall be $1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to our Board.

Plan Administration. The 2026 Plan is administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award, and to determine the specific terms and conditions of each award, subject to the provisions of the 2026 Plan. The compensation committee is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder approval.

Eligibility. Persons eligible to participate in the 2026 Plan are our employees, non-employee directors, and consultants and its affiliates selected from time to time by our compensation committee in its discretion.

Stock Options. The 2026 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option is determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option (i) is granted pursuant to a transaction described in and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to United States income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each option is fixed by our compensation committee and may not exceed ten years from the date of grant (or five years in the case of certain incentive stock options). Our compensation committee determines at what time or times each option may be exercised.

Stock Appreciation Rights. Our compensation committee may award stock appreciation rights under the 2026 Plan subject to such conditions and restrictions as it determines. Stock appreciation rights entitle the recipient to shares of our common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of our common stock on the date of grant unless the stock appreciation right (i) is granted pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to United States income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Restricted Stock and Restricted Stock Units. Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it determines. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or other service relationship with us through a specified vesting period.

Unrestricted Stock Awards. Our compensation committee may grant shares of common stock that are free from any restrictions under the 2026 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Dividend Equivalent Rights. Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Cash-Based Awards. Our compensation committee may grant cash bonuses under the 2026 Plan to participants, subject to the achievement of certain performance goals.

Sale Event. The 2026 Plan provides that, upon the effectiveness of a Sale Event (as defined in the 2026 Plan), an acquirer or successor entity may assume, continue, or substitute outstanding awards under the 2026 Plan. To the extent that awards granted under the 2026 Plan are not assumed, continued, or substituted by the successor entity, the 2026 Plan and all awards granted under the 2026 Plan will terminate. In such case, except as may be otherwise provided in the relevant award agreement, all awards with time-based vesting, conditions, or restrictions will become fully vested and exercisable or nonforfeitable as of the effective time of the Sale Event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and exercisable or nonforfeitable in connection with the Sale Event in the plan administrator's discretion or to the extent specified in the relevant award agreement. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise any options and stock appreciation rights (to the extent exercisable) within a specified time period, as determined by our compensation committee, prior to the Sale Event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the Sale Event and the exercise price of the options or stock appreciation rights; provided, that any options or stock appreciation rights with exercise prices equal to or greater than such per share consideration will be cancelled for no consideration. In addition, we may make or provide for a payment, in cash or in kind, to the participants holding other awards in an amount equal to the per share consideration payable to stockholders in the Sale Event multiplied by the number of vested shares of common stock under such awards.

Amendment. Our Board may amend or discontinue the 2026 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder's consent. Certain amendments to the 2026 Plan require the approval of our stockholders. Our compensation committee is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent.

No awards may be granted under the 2026 Plan after the date that is ten years from the effective date of the 2026 Plan.

2026 Employee Stock Purchase Plan

The 2026 ESPP was adopted by the Parent Board and approved by Parent's sole stockholder on June 30, 2026, and became effective on the date immediately preceding the closing of the Mergers. The 2026 ESPP has two components: a component intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code, or the 423 Component, and a component that is not intended to so qualify, or the Non-423 Component. Except as otherwise provided, the Non-423 Component will be operated and administered in the same manner as the 423 Component, except where prohibited by law. The following summary describes the material terms of the 2026 ESPP. This summary is not a complete description of all provisions of the 2026 ESPP and is qualified in its entirety by reference to the 2026 ESPP, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Authorized Shares. The 2026 ESPP initially reserves and authorizes the issuance of 7,494,541 that the number of shares reserved and available for issuance will automatically increase on January 1, 2027 and each January 1 thereafter through January 1, 2036 by the least of (i) the Initial ESPP Limit, (ii) 1% of the Outstanding Shares or (iii) such number of shares of our common stock as determined by the administrator of the 2026 ESPP. The number of shares reserved under the 2026 ESPP is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

Eligibility. All individuals classified as employees on our payroll records or a "designated company" (as defined in the 2026 ESPP) as of the first day of the applicable offering period are eligible to participate in the 2026 ESPP, provided that the administrator of the 2026 ESPP may determine in advance of an offering that employees are eligible only if, as of the first day of the offering, they (a) are customarily employed by us or a Designated Company (as defined in the ESPP) for more than 20 hours a week (or such lesser amount determined by the administrator of the 2026 ESPP), (b) are customarily employed by us or a Designated Company for more than five months per calendar year, (c) have completed a minimum period of employment as determined by the administrator of the 2026 ESPP, provided such service requirement does not exceed two years of employment, and/or (d) they are not highly compensated employees. However, any employee who owns, or as a result of participation in the 2026 ESPP would own or hold, 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of common stock under the 2026 ESPP.

Offerings. We may make one or more offerings each year to our employees to purchase shares of our common stock under the 2026 ESPP, each of which may consist of one or more purchase periods. Offerings will begin and end on the dates determined by the administrator of the 2026 ESPP, except that no offering will exceed 27 months in duration. Each eligible employee may elect to participate in any offering by submitting an enrollment form by the deadline established by the administrator of the 2026 ESPP.

Each employee who is a participant in the 2026 ESPP may purchase shares by authorizing payroll deductions at a minimum of 1% and up to a maximum of 15% of such participant's eligible compensation during an offering period (or such other minimum and maximum as determined by the administrator in advance of an offering). Unless the participating employee has previously withdrawn from the offering, such participant's accumulated payroll deductions will be used to purchase shares of our common stock on the last day of each purchase period at a price equal to 85% of the fair market value of the shares on the first day or the last day of the purchase period, whichever is lower, provided that no more than the number of shares of our common stock determined by dividing $25,000 by the fair market value of our common stock on the first day of such offering period (or such other maximum number of shares as may be established by the administrator of the 2026 ESPP) may be purchased by any one employee during any purchase period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of our common stock, valued at the start of the offering period, under the 2026 ESPP for each calendar year during which any option granted to the employee is outstanding at any time.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the 2026 ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

Sale Event. In the case of and subject to the consummation of a Sale Event (as defined in the 2026 ESPP), the administrator of the 2026 ESPP, in its discretion, and on such terms and conditions as it deems appropriate, is authorized to take any one or more of the following actions under the 2026 ESPP or with respect to any right under the 2026 ESPP or to facilitate such transactions or events: (i) provide for either (A) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (B) the replacement of such outstanding option with other options or property selected by the administrator of the 2026 ESPP in its sole discretion; (ii) provide that the outstanding options under the 2026 ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the

stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; (iii) make adjustments in the number and type of shares of common stock (or other securities or property) subject to outstanding options under the 2026 ESPP and/or in terms and conditions of outstanding options and options that may be granted in the future; (iv) provide that the offering with respect to which an option relates will be shortened by setting a new exercise date on which such offering period will end; and (v) provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

Amendment. The 2026 ESPP may be terminated or amended by our Board at any time. An amendment that increases the number of shares of our common stock authorized under the 2026 ESPP and certain other amendments require the approval of our stockholders.

Senior Executive Cash Incentive Bonus Plan

On June 22, 2026, our Board adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon our and individual performance targets established by our compensation committee. The performance targets will be related to our financial or operational measures or objectives, or Corporate Performance Goals, as well as individual performance objectives. The following summary describes the material terms of the Bonus Plan. This summary is not a complete description of all provisions of the Bonus Plan and is qualified in its entirety by reference to the Bonus Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Our compensation committee may select Corporate Performance Goals from among the following: research and development, publication, clinical, and/or regulatory milestones; revenue; corporate revenue; earnings before interest, taxes, depreciation, and amortization; net income (loss) (either before or after interest, taxes, depreciation, and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions or strategic transactions, including licenses, collaborations, joint ventures, or promotion arrangements; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention and recruiting, and other human resources matters; operating income; and/or net annual recurring revenue; or any other performance goal selected by our compensation committee, any of which may be (A) measured in absolute terms or as compared to any incremental increase, (B) measured in terms of growth, as compared to results of a peer group, or (C) measured against the market as a whole, compared to applicable market indices, and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but not later than 74 days after the end of the year in which such performance period ends. Subject to any rights contained in any agreement between the executive officer and us, an executive officer shall be required to be employed by us on the bonus payment date to be eligible to receive a bonus payment under the Bonus Plan. The Bonus Plan also permits our compensation committee to approve additional bonuses to executive officers in its sole discretion.

Director Compensation

The following table presents the compensation awarded to, earned by, or paid to each person who served as a non-employee member of the Legacy Obsidian Board for their services to Legacy Obsidian during Fiscal Year

2025. Other than as set forth in the table and described more fully below, Legacy Obsidian did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of the Legacy Obsidian Board in Fiscal Year 2025. During the Fiscal Year 2025, Legacy Obsidian did not have a formal non-employee director compensation program; however, in the Fiscal Year 2025, Dr. Fardis received $50,000 in cash compensation for her services as chairperson of the Legacy Obsidian Board, Ms. Hagen and Dr. Ross each received $25,000 in cash compensation for service as an independent director and Dr. Norkunas received $35,000 in cash compensation for service as an independent director and chair of the audit committee of the Legacy Obsidian Board. We reimburse non-employee members of the Legacy Obsidian Board for reasonable travel and out-of-pocket expenses incurred in attending meetings of the Legacy Obsidian Board and committees of the Legacy Obsidian Board. Dr. Jagasia, who is our Chief Executive Officer, did not receive any additional compensation for his service as a director, and Dr. Barrett, who serves on the Legacy Obsidian Board as a representative of a fund that is an investor in Legacy Obsidian, did not receive cash or equity compensation from Legacy Obsidian in Fiscal Year 2025 and, accordingly, he has been omitted from the table below. The compensation received by Dr. Jagasia, as a named executive officer of Legacy Obsidian, is presented in "*2025 Summary Compensation Table*" above.

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2) (3)	Total ($)
Robert Ross	25,000	17,332	42,332
Heidi Hagen	25,000	27,093	52,093
Maria Fardis	50,000	60,909	110,909
Matthew Norkunas	35,000	10,721	45,721

(1) The amounts reported represent the cash fees each director received for their services to the Legacy Obsidian Board during Fiscal Year 2025.

(2) The amount reported represents the aggregate incremental fair value related to the repricing, in Fiscal Year 2025, of certain stock option awards held by the non-employee directors that were granted prior to Fiscal Year 2025, computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the incremental fair values include a common stock fair value of $0.78, a risk-free interest rate ranging from 4.03% to 4.14%, an expected dividend yield of 0.00%, an expected term of 3.2 to 5.2 years, and an expected volatility ranging from 76.86% to 80.18%. The amounts reported in this column reflect the accounting cost for the repricing of certain option awards and do not correspond to the actual economic value that may be received by our non-employee directors upon the exercise of the option awards or any sale of the underlying securities.

(3) As of December 31, 2025, each non-employee director held options to purchase the aggregate number of shares of common stock as set forth below:

Name	Shares Underlying Outstanding Option Awards
Robert Ross	517,500
Heidi Hagen	517,500
Maria Fardis	1,222,500
Matthew Norkunas	262,500

None of our non-employee directors held stock awards other than options as of December 31, 2025.

Non-Employee Director Compensation Policy

In connection with the Mergers, Parent adopted a non-employee director compensation policy that became effective upon the completion of the Mergers and is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee is paid cash compensation following the completion of the Mergers, as set forth below, which amounts are payable quarterly in arrears and prorated for partial years of service:

Board of Directors:	Annual Retainer
Members	$ 40,000
Additional retainer for non-executive chair	$ 30,000

Audit Committee:	Additional Amount
Members (other than chair)	$ 10,000
Retainer for chair	$ 20,000
Compensation Committee:	
Members (other than chair)	$ 7,500
Retainer for chair	$ 15,000
Nominating and Corporate Governance Committee:	
Members (other than chair)	$ 5,000
Retainer for chair	$ 10,000

In addition, the non-employee director compensation policy provides that, upon initial election to our Board, each non-employee director will be granted an initial stock option award to purchase a number of shares of our common stock equal to 0.122% of the total number of outstanding shares of our common stock on the date of grant, or the Initial Grant. The Initial Grant will vest in equal monthly installments over three years following the date of grant, subject to continued service through the applicable vesting date. Furthermore, upon the closing of the Mergers and on the date of each annual meeting of stockholders following the completion of the Mergers, each non-employee director who is serving as a non-employee director as of the closing of the Mergers or who continues as a non-employee director following such meeting, as applicable, was or will be (as applicable) granted an annual stock option award to purchase a number of shares of our common stock equal to 0.061% of the total number of outstanding shares of our common stock on the date of grant, or the Annual Grant. The Annual Grant will vest in full on the earlier of the first anniversary of the date of grant and our next annual meeting of stockholders, subject to continued service through the applicable vesting date. All outstanding awards granted to non-employee directors will become fully vested and exercisable upon a Sale Event (as defined in the 2026 Plan).

The grant date fair value of all awards and all other cash compensation paid by us to any non-employee director during any one calendar year for services as a non-employee director may not exceed $750,000; provided, however, that such amount shall be $1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to our Board.

We reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board and committees thereof.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Obsidian Therapeutics, Inc. (formerly Gazelle Parent, Inc.) was incorporated on April 14, 2026 and therefore was not a party to any related person transactions during the periods presented below (except for the PIPE Financing described below). Accordingly, the historical related person transaction disclosure below relates to transactions involving Legacy Obsidian. The following is a description of transactions or series of transactions since January 1, 2023, to which Legacy Obsidian (referred to herein as "we," "our" or "Legacy Obsidian") was a party, in which:

- the amount involved in the transaction exceeds, or will exceed, $120,000; and
- in which any of our executive officers, directors or holder of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under the sections titled "*Executive Compensation*" and "*Director Compensation*."

PIPE Financing

On April 14, 2026, Parent, Legacy Obsidian and Legacy Galera entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain qualified institutional buyers and/or accredited investors, or the Investors. Pursuant to the Securities Purchase Agreement, and subject to the terms and conditions therein, the Investors agreed to purchase, and Legacy Galera agreed to issue and sell, immediately prior to the effective time of the Obsidian Merger, shares of Legacy Galera's Series C Non-Voting Convertible Preferred Stock, par value $0.001 per share, or the Series C Preferred Stock, for an aggregate purchase price of $350.0 million, or the PIPE Financing. The PIPE Financing closed on July 31, 2026. On August 3, 2026, each outstanding share of Legacy Galera common stock (including those resulting from the conversion of the preferred stock and pre-funded warrants, but excluding dissenting shares and certain excluded shares as described in the prospectus filed by the Parent on July 2, 2026) was converted into the right to receive a number of shares of Parent Common Stock calculated as described in the prospectus filed by the Parent on July 2, 2026. The following table summarizes purchases of the Legacy Galera preferred stock, as converted to Legacy Galera common stock and ultimately exchanged for Parent Common Stock by related persons:

Participant	Affiliated Director(s) or Officer(s)	Shares of Parent Common Stock	Total Original Purchase Price
RA Capital and its Affiliates(1)	—	3,124,859	$ 37,499,641.20
Atlas Venture Fund and its Affiliates(2)	—	208,324	$ 2,500,000.00
Deep Track Biotechnology Master Fund, Ltd.(3)	—	833,296	$ 10,000,000.00
Novo Holdings A/S(4)	—	1,666,592	$ 20,000,000.00

(1) Entities affiliated with RA Capital Management, L.P., or RA Capital, collectively hold five percent or more of our capital stock.
(2) Atlas Venture Opportunity Fund III, L.P. is affiliated with Atlas Venture Life Science Advisors, LLC, or Atlas Venture. Entities affiliated with Atlas Venture collectively hold five percent or more of our capital stock.

(3) Such entity holds five percent or more of our capital stock.
(4) Such entity holds five percent or more of our capital stock.

In connection with the Securities Purchase Agreement, Parent and, Legacy Galera also entered into the 2026 PIPE Registration Rights Agreement with the PIPE Financing investors, pursuant to which we agreed to prepare and file this resale registration statement with the SEC within 30 calendar days following the closing of the PIPE Financing.

Private Placement of Securities

In April 2024, Deep Track Biotechnology Master Fund, Ltd. a holder of five percent or more of Legacy Obsidian's capital stock, purchased shares of Legacy Obsidian common stock, par value $0.0001 per share from Legacy Obsidian's former chief legal officer, Lee Giguere, Legacy Obsidian's former chief financial officer, Ryan Daws, and certain of Legacy Obsidian's other former employees, in the amounts of 721,130 shares of Legacy Obsidian common stock, 1,349,735 shares of Legacy Obsidian common stock, 1,359,135 shares of Legacy Obsidian common stock, respectively, in a secondary offering at a purchase price of $1.75 per share for aggregate gross proceeds of approximately $6.0 million.

In September 2024, Soleus Private Equity Fund II, L.P., a holder of Legacy Obsidian's capital stock, purchased shares of Legacy Obsidian common stock from a former director, Jason Gardner, and a former employee, in the amounts of 328,750 shares of Legacy Obsidian common stock and 175,438 shares of Legacy Obsidian common stock, respectively, in a secondary offering at a purchase price of $1.85 per share for an aggregate gross proceeds of approximately $933,000.

Series C Redeemable Convertible Preferred Stock Financing

In March 2024, Legacy Obsidian sold an aggregate of 84,567,145 shares of its Series C redeemable convertible preferred stock at a purchase price of $1.8979 per share for an aggregate purchase price of approximately $160.5 million. The following table summarizes purchases of Legacy Obsidian's Series C redeemable convertible preferred stock by related persons:

Participant	Affiliated Director(s) or Officer(s)	Shares of Series C Redeemable Convertible Preferred Stock	Total Approx. Purchase Price
Entities affiliated with Atlas Venture(1)	—	4,215,185	$ 8,000,000
TCG Crossover Fund I, L.P.(2)	Cariad Chester	2,634,490	$ 4,999,999
Entities affiliated with RA Capital(3)	—	9,220,717	$17,499,999
Deep Track Biotechnology Master Fund, Ltd.(4)	—	9,220,717	$17,499,999
Celgene Corporation(5)	—	2,107,592	$ 3,999,999

(1) Atlas Venture Opportunity Fund II, L.P. is affiliated with Atlas Venture. Entities affiliated with Atlas Venture collectively hold five percent or more of our capital stock.
(2) Such entity held five percent or more of Legacy Obsidian's capital stock. Mr. Chester is a managing partner at TCG Crossover Fund I, L.P., or TCGX, and was member of the Legacy Obsidian Board.
(3) Entities affiliated with RA Capital, collectively hold five percent or more of our capital stock.
(4) Such entity holds five percent or more of our capital stock.
(5) Such entity held five percent or more of Legacy Obsidian's capital stock.

Agreements with Our Stockholders

Celgene Corporation

In January 2019, Legacy Obsidian entered into a Master Collaboration Agreement with Celgene Corporation and Celgene Switzerland LLC, which was amended in September 2020, December 2021, and October 2022, or the Celgene Agreement. In September 2020, Legacy Obsidian entered into a First Program Global License Agreement with Celgene Corporation and Celgene Switzerland LLC, or the Celgene License. Celgene Corporation was a holder of greater than five percent of Legacy Obsidian's capital stock. In connection with the execution of the Celgene Agreement and certain option exercises and extensions under the Celgene Agreement, Legacy Obsidian received an aggregate of $95.0 million since 2019. The Celgene Agreement and Celgene License were each terminated on October 21, 2025 and November 3, 2025, respectively, at which time the collaboration and all rights under the Celgene Agreement and Celgene License were terminated.

Vertex Pharmaceuticals Incorporated

Between August 2021 and March 2024, Vertex Pharmaceuticals Incorporated, or Vertex Pharmaceuticals, was a holder of greater than five percent of Legacy Obsidian's capital stock. In April 2021, Legacy Obsidian entered into a four-year collaboration and license arrangement with Vertex Pharmaceuticals, or the Vertex Agreement. Under the Vertex Agreement, Legacy Obsidian conducted *in vitro* research to discover drug-responsive domain constructs for regulated gene editing. During the term of the collaboration, Vertex Pharmaceuticals held an option to obtain certain rights to develop, manufacture, and commercialize gene editing products discovered under the Vertex Agreement. Over the term of the agreement, Legacy Obsidian received an aggregate of $27.5 million in an up-front payment and in consideration for achieving a research milestone for one disease. The Vertex Agreement expired on April 16, 2025, at which time the collaboration and all rights under the Vertex Agreement were terminated.

Agreements with Other Stockholders

In connection with Legacy Obsidian's redeemable convertible preferred stock financings, Legacy Obsidian entered into an investors' rights agreement, voting agreement and right of first refusal and co-sale agreement, in each case, with the purchasers of Legacy Obsidian's redeemable convertible preferred stock and certain holders of Legacy Obsidian's common stock.

Legacy Obsidian's amended and restated investors' rights agreement, or the Investors' Rights Agreement, provided certain holders of Legacy Obsidian's capital stock with the right to demand that Legacy Obsidian file a registration statement, subject to certain limitations, and to request that their shares be covered by a registration statement that Legacy Obsidian is otherwise filing. The rights under the Investor's Rights Agreement terminated upon the closing of the Mergers.

Legacy Obsidian's amended and restated voting agreement, the Voting Agreement, provided drag-along rights in respect of sales by certain holders of Legacy Obsidian's capital stock. The Voting Agreement also contained provisions with respect to the elections of the Legacy Obsidian Board and its composition. The rights under the Voting Agreement terminated upon the closing of the Mergers.

Legacy Obsidian's amended and restated right of first refusal and co-sale agreement, or the Right of First Refusal and Co-Sale Agreement, provided for rights of first refusal and co-sale rights in respect of sales by certain holders of Legacy Obsidian's capital stock. The rights under the Right of First Refusal and Co-Sale Agreement terminated upon the closing of the Mergers.

Indemnification Agreements

We have entered into agreements to indemnify our directors and executive officers. These agreements, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our Company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Related Person Transaction Policy

Our audit committee reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. The material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

We have adopted a written related party transactions policy that such transactions must be approved by our audit committee.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

The following table sets forth certain information regarding beneficial ownership of our common stock immediately after consummation of the PIPE Financing and the Mergers for: each beneficial owner of more than 5% of our outstanding common stock, each of our named executive officer, each of our director, and all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power with respect to the securities as well as any shares of common stock that the individual or entity has the right to acquire within 60 days following the closing of the Mergers upon the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

The table lists applicable percentage ownership based on 61,772,876 shares of common stock outstanding on August 3, 2026, after giving effect to the PIPE Financing and giving effect to the Legacy Galera Reverse Stock Split. The number of shares beneficially owned includes shares of common stock that each person has the right to acquire within 60 days, including upon the exercise of stock options and the vesting of restricted stock units. Except as otherwise noted in the footnotes below, the address of each holder is c/o Obsidian Therapeutics, 1030 Massachusetts Ave., Cambridge, MA 02138.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders:		
Entities affiliated with RA Capital (1)	5,957,103	9.64%
Entities affiliated with Atlas Venture (2)	4,503,149	7.29%
Deep Track Biotechnology Master Fund, Ltd. (3)	3,315,605	5.37%
Novo Holdings A/S (4)	3,123,992	5.06%
Directors and Named Executive Officers:		
Madan Jagasia, M.D., M.S. (5)	1,287,220	2.04%
Parameswaran Hari, M.D., M.S. (6)	328,033	*%
Dana Alexander, M.B.A. (7)	208,086	*%
Maria Fardis, Ph.D., M.B.A. (8)	138,970	*%
Heidi Hagen, M.B.A. (9)	51,149	*%
Matthew Norkunas, M.D., M.B.A. (10)	28,200	*%
Robert Ross, M.D. (11)	61,739	*%
Peter Barrett, Ph.D.	—	—
All executive officers and directors as a group (9 persons) (12)	2,122,178	3.32%

* Represents beneficial ownership of less than 1%.

(1) Consists of 5,957,103 shares of common stock held by entities affiliated with RA Capital Management, L.P. RA Capital Management, L.P., is the investment manager for RA Capital Nexus Fund II, L.P., and RA Capital Healthcare Fund, L.P. Peter Kolchinsky, Ph.D. and Rajeev Shah are the managing members of RA Capital Management GP, LLC. Each of Dr. Kolchinsky and Mr. Shah disclaims beneficial ownership of the securities held by RA Capital Nexus Fund II, L.P., and RA Capital Healthcare Fund, L.P., except to the extent of any pecuniary interest therein, if any. The address of RA Capital Nexus Fund II, L.P., and RA Capital Healthcare Fund, L.P., is 200 Berkeley Street, 18th Floor, Boston MA 02116.

(2) Consists of 4,503,149 shares of common stock held by entities affiliated with Atlas Venture Fund. The general partner of Atlas I is Atlas Venture Associates Opportunity I, L.P., or AVAO I, and the general

partner of AVAO I is Atlas Venture Associates Opportunity I, LLC, or AVAO I LLC. The general partner of Atlas II is Atlas Venture Associates Opportunity II, L.P., or AVAO II, and the general partner of AVAO II is Atlas Venture Associates Opportunity II, LLC, or AVAO II LLC. The general partner of Atlas Venture Opportunity Fund III, L.P., or AVOF III, is Atlas Venture Associates Opportunity III, L.P., or AVAO III LP, and Atlas Venture Associates Opportunity III, LLC, or AVAO III LLC is the general partner of AVAO III LP. Each of AVOF III, AVAO III LP and AVAO III LLC may be deemed to beneficially own the shares held by AVOF III. The general partner of Atlas X is Atlas Venture Associates X, L.P., or AVA X, and the general partner of AVA X is Atlas Venture Associates X, LLC, or AVA X LLC. Kevin Bitterman, Ph.D., is a member of AVAO I LLC and AVAO II LLC. Michael Gladstone is a member of AVAO II LLC. Bruce Booth, D.Phil., David Grayzel, M.D., Jean-Francois Formela, M.D. and Jason Rhodes are members of AVA X LLC, AVAO I LLC and AVAO II LLC. By virtue of these relationships, each of AVA X, AVA X LLC, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC may be deemed to beneficially own the shares held by Atlas I or Atlas II or Atlas X, and each expressly disclaims beneficial ownership of such shares except to the extent of its pecuniary interest therein, if any. Dr. Bitterman, Dr. Booth, Dr. Grayzel, Dr. Formela and Mr. Rhodes may be deemed to beneficially own the shares held by Atlas I and Atlas II, and each expressly disclaims beneficial ownership of such shares except to the extent of its pecuniary interest therein, if any. Mr. Gladstone may be deemed to beneficially own the shares held by Atlas II, and each expressly disclaims beneficial ownership of such shares except to the extent of its pecuniary interest therein, if any. Dr. Booth, Mr. Rhodes, Dr. Bitterman and Mr. Gladstone may be deemed to beneficially own the shares held by Atlas III, and each expressly disclaims beneficial ownership of such shares except to the extent of its pecuniary interest therein, if any. Dr. Booth, Dr. Grayzel, Dr. Formela and Mr. Rhodes may be deemed to beneficially own the shares held by Atlas X, and each expressly disclaims beneficial ownership of such shares except to the extent of its pecuniary interest therein, if any. The address of Atlas I, Atlas II, Atlas III, Atlas X, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC, AVAO III, AVAO III LLC, AVA X and AVA X LLC is 300 Technology Square, 8th Floor, Cambridge, MA 02139.

(3) Consists of 3,315,605 shares of common stock held by Deep Track Biotechnology Master Fund, Ltd., or Deep Track. The address of Deep Track is 200 Greenwich Avenue, 3rd Floor, Greenwich, CT 06830.

(4) Consists of 3,123,992 shares of common stock held by Novo Holdings A/S. The address of Novo Holdings A/S is Tuborg Havnevej 19, DK 2900, Hellerup, Denmark.

(5) Consists of options to purchase 1,287,220 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

(6) Consists of options to purchase 328,033 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

(7) Includes options to purchase 208,086 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

(8) Includes options to purchase 138,970 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

(9) Includes options to purchase 51,149 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

(10) Includes options to purchase 28,200 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

(11) Includes options to purchase 61,739 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

(12) Includes options to purchase 2,117,899 shares of common stock that are outstanding and exercisable as of August 3, 2026, or exercisable within 60 days of August 3, 2026.

SELLING STOCKHOLDERS

The selling stockholders acquired shares of common stock from us in the Mergers upon exchange of shares of Legacy Galera acquired from Legacy Galera immediately prior to the Mergers pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act. Under the registration rights agreement that we assumed in the Mergers, we agreed to file a registration statement with the SEC for the purposes of registering for resale from time to time the shares of common stock.

Except for the ownership of shares of common stock received in the Mergers and as discussed below, the selling stockholders have not had any material relationship with our company within the past three years.

The table below lists the selling stockholders and other information regarding their ownership of the shares of common stock offered hereby. The first column lists the number of shares of common stock beneficially owned by the selling stockholders as of August 3, 2026 immediately following the closing of the Mergers. The selling stockholders may have sold or transferred some or all of the common stock indicated below and may in the future sell or transfer some or all of the common stock indicated below in transactions exempt from the registration requirements of the Securities Act rather than under this prospectus. The second column lists the shares of common stock being offered by this prospectus by the selling stockholders. The third column assumes the sale of all of the shares of common stock offered by the selling stockholders pursuant to this prospectus. The selling stockholders may sell all, some or none of their shares of common stock in this offering. See "*Plan of Distribution*."

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the selling stockholders have sole voting and investment power with respect to all shares of common stock that they own, subject to applicable community property laws. Beneficial ownership for the purposes of the table below is determined in accordance with the rules and regulations of the SEC. These rules generally provide that a person is the beneficial owner of securities if such person has or shares the power to vote or direct the voting thereof, or to dispose or direct the disposition thereof or has the right to acquire such powers within 60 days. Percentage of beneficial ownership is based on 61,772,876 shares of common stock outstanding as of August 3, 2026 immediately following the closing of the Mergers.

Selling Stockholders	Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Being Offered Hereby	Common Stock Beneficially Owned After the Shares Offered Hereby are Sold	
			Number	Percent
Atlas Private Holdings (Cayman) Ltd. (1)	1,083,243	1,083,243	0	*
Caligan Partners Master Fund LP(2)	1,499,752	1,499,752	0	*
Entities affiliated with Deep Track(3)	3,315,605	833,296	2,482,309	4.02%
Eventide Healthcare Innovation Fund I LP(4)	624,972	624,972	0	*
Franklin and its Affiliates(5)	833,297	833,297	0	*
Janus and its Affiliates(6)	2,395,293	1,666,593	728,700	1.18%
Nantahala and its Affiliates(7)	1,124,796	1,124,796	0	*
Novo Holdings A/S(8)	3,123,992	1,666,592	1,457,400	2.36%
Octagon Investments Master Fund LP(9)	2,499,888	2,499,888	0	*

Selling Stockholders	Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Being Offered Hereby	Common Stock Beneficially Owned After the Shares Offered Hereby are Sold	
			Number	Percent
Entities associated with Paradigm(10)	2,666,130	2,083,170	582,960	*
Entities associated with Pivotal(11)	1,799,411	1,249,875	549,536	*
RA Capital and Associates(12)	5,957,103	3,124,859	2,832,244	4.58%
Entities affiliated with Redmile Group, LLC(13)	833,157	833,157	0	*
Entities affiliated with RTW(14)	1,249,555	666,595	582,960	*
Entities affiliated with Spruce Street(15)	1,249,945	1,249,945	0	*
Citadel CEMF Investments Ltd.(16)	666,595	666,595	0	*
Trails Edge Biotechnology Master Fund, LP(17)	2,374,879	2,374,879	0	*
Wellington Biomedical Innovation Master Investors (Cayman) II L.P. (18)	2,123,995	666,595	1,457,400	2.36%
Certain Unnamed Non-Affiliate Selling Stockholders (19)	15,183,713	4,415,946	10,767,767	17.43%
Total	**50,605,303**	**29,164,045**	**21,441,258**	**34.71%**

(1) Balyasny Asset Management L.P. is the investment adviser of Atlas Private Holdings (Cayman) Ltd. Dmitry Balyasny, via intermediate entities, manages Balyasny Asset Management L.P. and has voting and investment control over the reported securities. The address for Atlas Private Holdings (Cayman) Ltd. and Balyasny Asset Management L.P. is 444 West Lake Street, 50th Floor, Chicago, IL 60606.

(2) Consists of (i) 1,187,896 shares of common stock purchased by Caligan Partners Master Fund LP, (ii) 190,426 shares of common stock purchased by Boothbay Absolute Return Strategies LP, (iii) 89,984 shares of common stock purchased by Boothbay Diversified Alpha Master Fund LP and (iv) 31,446 shares of common stock purchased by Highvista Biotechnology SMA Fund LP, or, together, the Caligan Funds, in the PIPE Financing. Caligan Partners, LP, or Caligan, serves indirectly as the investment manager to the Caligan Funds, and certain related managed accounts represented in this row. David Johnson is the Managing Partner of Caligan and the Managing Member of Caligan Partners GP LLC, the general partner of Caligan, and may be deemed to have voting and investment power over the securities held by Caligan and the Caligan Funds.

(3) Shares of our common stock beneficially owned prior to the offering represent (i) 640,555 shares of common stock purchased by Deep Track Biotechnology Master Fund, Ltd. and 192,741 shares of common stock purchased by Deep Track Special Opportunities Fund, LP., or, together with Deep Track Biotechnology Master Fund, Ltd., Deep Track, in the PIPE Financing and (ii) 2,482,309 shares of common stock held by Deep Track. David Kroin is the managing member of Deep Track Capital GP, LLC, or the GP. The GP is the general partner of Deep Track Capital, LP, or the IM. The IM is the investment manager of Deep Track Biotechnology Master Fund, Ltd.

(4) Eventide Healthcare Innovation Fund I GP LLC, or the GP, is the general partner of Eventide Healthcare Innovation Fund I LP, or EHIF I, and may be deemed to have voting and investment power over the shares held by EHIF I. Eventide Asset Management, LLC, or Eventide, the Managing Member of the GP, and Robin John, Chief Executive Officer of Eventide, may also be deemed to have voting and investment power over the shares held by EHIF I. Finny Kuruvilla and I-hing Shih are members of EHIF I's Investment Committee and may be deemed to share voting and investment power over the shares held by EHIF I. Each of the GP, Eventide, Mr. John, Mr. Kuruvilla, and Ms. Shih disclaims beneficial ownership of such shares except to the extent of their respective pecuniary interests therein. The address of EHIF I is c/o Eventide Asset Management, LLC, 1 International Place, Suite 4210, Boston, MA 02110.

(5) Franklin Advisers, Inc., is the investment adviser to Franklin Templeton Investment Funds - Franklin Biotechnology Discovery Fund, or Franklin Templeton. Franklin Templeton has one or more portfolio managers appointed by and serving at the pleasure of Franklin Templeton who make decisions with respect to the disposition of the shares of Common Stock offered hereby.

(6) Shares of our common stock beneficially owned prior to the offering represent (i) 1,370,250 shares of common stock purchased by the Janus Henderson Biotech Innovation Master Fund Limited and 296,343 shares of common stock purchased by Janus Henderson Biotech Innovation Master Fund II Limited, or, together, the Janus Funds, in the PIPE Financing and (ii) 728,700 shares of common stock held by the Janus Funds. The shares held by the Janus Funds may be deemed to be beneficially owned by Janus Henderson Investors US LLC, or Janus, an investment adviser registered under the Investment Advisers Act of 1940, who acts as investment adviser for the Janus Funds and has the ability to make decisions with respect to the voting and disposition of the shares subject to the oversight of the board of directors of the Janus Funds. Under the terms of its management contracts with the Janus Funds, Janus has overall responsibility for directing the investments of the Janus Funds in accordance with the Janus Funds' investment objective, policies and limitations. The Janus Funds have one or more portfolio managers appointed by and serving at the pleasure of Janus who make decisions with respect to the disposition of the shares of Common Stock offered hereby. The address for Janus is 151 Detroit Street, Denver, CO 80206. The portfolio managers for the Janus Funds are: Andrew Acker, Daniel S. Lyons and Agustin Mohedas.

(7) Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder.

(8) Shares of our common stock beneficially owned prior to the offering represent (i) 1,666,592 shares of common stock purchased by Novo Holdings A/S (as defined below) in the PIPE Financing and (ii) 1,457,400 shares of common stock held by Novo Holdings A/S. Novo Holdings A/S has the sole power to vote and dispose of the shares, and no individual or other entity is deemed to hold any beneficial ownership in the shares.

(9) Octagon Capital Advisors LP is the investment advisor of Octagon Investments Master Fund LP. Ting Jia, as the managing member of Octagon Capital Advisors LP, may be deemed to beneficially own the shares of common stock held by Octagon Investments Master Fund LP. The address of this entity is 654 Madison Avenue, 21st Floor, New York, NY 10065.

(10) Consists of (i) 2,409,936 shares of Common Stock held by Paradigm BioCapital International Fund Ltd., or Paradigm BioCapital Fund, and (ii) 256,194 shares of Common Stock held by Paradigm BioCapital Advisors LP, as discretionary investment manager on behalf of a separate account client solely with respect to the assets for which Paradigm BioCapital Advisors LP acts as its investment manager, or the Separate Account. The shares of Common Stock may be deemed to be indirectly beneficially owned by each of Paradigm BioCapital Advisors LP, Paradigm BioCapital Advisors GP LLC, and Senai Asefaw, M.D. Paradigm BioCapital Advisors GP LLC is the general partner of Paradigm BioCapital Advisors LP, and Senai Asefaw, M.D. is the managing member of Paradigm BioCapital Advisors GP LLC. Paradigm

BioCapital Advisors LP is the investment manager of Paradigm BioCapital Fund. Paradigm BioCapital Advisors LP, Paradigm Advisors GP LLC, and Senai Asefaw, M.D. may be deemed to have full investment and voting discretion over the shares of Common Stock held by Paradigm BioCapital Fund and the Separate Account. The address for Paradigm BioCapital Advisors LP is 520 Fifth Avenue, 23rd Floor, New York, NY 10036. The address for Paradigm BioCapital Fund is c/o Walkers Corporate Limited, 190 Elgin Avenue, George Town, Grand Cayman, KY1-9008, Cayman Islands.

(11) Shares of our common stock beneficially owned prior to the offering represent (i) 1,249,875 shares of common stock purchased by Pivotal bioVenture Partners Fund I, L.P. and its affiliate Permwell Management Limited in the PIPE Financing and (ii) 549,536 shares of common stock held by Pivotal bioVenture Partners Fund I, L.P. Investment and voting decisions with respect to the securities held by Pivotal bioVenture Partners Fund I, L.P. and Permwell Management Limited are made by Mr. Vincent Sai Sing Cheung, Mr. Peter Bisgaard, and Dr. Robert Hopfner, who are both the members of the Investment Committee of Pivotal bioVenture Partners Fund I G.P., L.P. and the individuals with make investment and voting decisions for shares of the Company's securities held by Permwell Management Limited.

(12) Shares of our common stock beneficially owned prior to the offering represent (i) 2,968,616 shares of common stock purchased by RA Capital Healthcare Fund, L.P., or RACHF, and 156,243 shares of common stock purchased by RA Capital Nexus Fund IV, L.P., or Nexus, and together, the RA Funds, in the PIPE Financing and (ii) 2,832,244 shares of common stock held by the RA Funds. RA Capital Management, L.P., RACM, is the investment manager for RACHF and Nexus. The general partner of RACHF is RA Capital Healthcare Fund GP, LLC and the general partner of Nexus is RA Capital Nexus Fund III GP, LLC. Peter Kolchinsky and Rajeev Shah are the managing members of such general partners. Each of RACM, RA Capital Healthcare Fund GP, LLC, RA Capital Nexus Fund III GP, LLC, Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the shares held by the RA Funds. RACM, RA Capital Healthcare Fund GP, LLC, RA Capital Nexus Fund III GP, LLC, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The principal business address of the persons and entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(13) Consists of (i) 144,381 shares of common stock purchased by Redmile Capital Fund, LP, (ii) 355,653 shares of common stock purchased by Redmile Capital Offshore Master Fund, Ltd., (iii) 164,807 shares of common stock purchased by Redmile Strategic Long Only Trading Sub, Ltd. and (iv) 168,316 shares of common stock purchased by Redmile Strategic Trading Sub, Ltd. in the PIPE Financing. Redmile Group, LLC, or Redmile, is the investment manager to Redmile Capital Fund, LP, Redmile Capital Offshore Master Fund, Ltd., Redmile Strategic Long Only Trading Sub, Ltd. and Redmile Strategic Trading Sub, Ltd., or, collectively, the Redmile Funds, and in such capacity, exercises voting and investment power over all of the securities held by such entities and may be deemed to be the beneficial owner of these securities. Jeremy C. Green serves as the principal of Redmile and also may be deemed to be the beneficial owner of these securities. Redmile and Mr. Green each disclaim beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any. The address of the Redmile Funds is c/o Redmile Group, LLC, 900 Larkspur Landing Circle, Suite 270, Larkspur, CA 94939.

(14) Shares of our common stock beneficially owned prior to the offering represent (i) 346,879 shares of common stock purchased by RTW Master Fund, Ltd., 288,060 shares of common stock purchased by RTW Innovation Master Fund, Ltd. and 31,656 shares of common stock purchased by RTW Biotech Opportunities Operating Ltd., or, together, the RTW Funds, in the PIPE Financing and (ii) 582,960 shares of common stock held by the RTW Funds. RTW Investments, LP, or RTW, in its capacity as the investment manager of the RTW Funds has the power to vote and the power to direct the disposition of the shares held by the RTW Funds. Accordingly, RTW may be deemed to be the beneficial owner of such securities. Roderick Wong, M.D., as the Managing Partner of RTW, has the power to direct the vote and disposition of the securities held by RTW. Dr. Wong disclaims beneficial ownership of the shares held by the RTW Funds, except to the extent of his pecuniary interest therein. The address and principal office of RTW Investments, LP is 40 10th Avenue, Floor 7, New York, NY 10014, and the address of Dr. Wong and each of the RTW Funds is c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014.

(15) Consists of (i) 219,485 shares of common stock purchased by MAP 852 SP, a segregated portfolio of MAP Institutional SPC and (ii) 1,030,460 shares of common stock purchased by Spruce Street Capital Master Fund LPin the PIPE Financing. Spruce Street Capital LP, or Spruce Street, is the investment manager of Spruce Street Master Fund LP, and of MAP 852 SP. Simon Basseyn and Alex Rosen are the managing partners of Spruce Street. These individuals may be deemed to have shared voting and investment power of the securities held by Spruce Street Master Fund LP and MAP 852 SP. Each of these individuals disclaims beneficial ownership of such securities, except to the extent of his or her pecuniary interest therein. The business address of each of the individuals and entities referenced in this footnote is 777 Third Avenue, Suite 1704, New York, NY 10017.

(16) Citadel Advisors LLC is the portfolio manager of Citadel CEMF Investments Ltd. Citadel Advisors Holdings LP, or CAH, is the sole member of Citadel Advisors LLC. Citadel GP LLC, or CGP, is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP. Mr. Griffin, as the owner of a controlling interest in CGP, may be deemed to have shared power to vote or direct the vote of, and/or shared power to dispose or to direct the disposition over, the Registrable Securities covered by this Questionnaire. This response is not and shall not be construed as an admission that Mr. Griffin or any of the Citadel related entities listed above is the beneficial owner of any securities of the Company other than the securities actually owned by such person (if any).

(17) Trails Edge Capital Partners, LP, or Trails Edge Capital, as the investment manager to Trails Edge Biotechnology Master Fund, LP, or Trails Edge Biotechnology, may be deemed to beneficially own these securities. Mr. Yehudai, as the Chief Investment Officer of Trails Edge Capital, exercises voting and investment discretion with respect to these securities and as such may be deemed to beneficially own such securities. The address of these funds and persons is 3445 Peachtree Road NE, Suite 900, Atlanta, GA 30326.

(18) Shares of our common stock beneficially owned prior to the offering represent (i) 666,595 shares of common stock purchased by Wellington Management Company LLP in the PIPE Financing and (ii) 1,457,400 shares of common stock held by Wellington Management Company LLP. The Stockholder is not affiliated with a broker-dealer participating in retail brokerage, lending, or securities underwriting. The stockholder is advised by Wellington Management Company LLP, or WMC, a registered investment adviser. WMC has the power to vote and dispose the securities pursuant to WMC's investment management agreement with the stockholder. Wellington Management Company LLP is under common control with Wellington Funds Distributors Inc., a limited-scope broker-dealer registered with FINRA and organized under the laws of Delaware. Wellington Funds Distributors Inc. does not engage in retail brokerage, lending, or securities underwriting.

(19) Certain selling stockholders that are not our affiliates and that, together with their respective affiliates, hold less than 1% of the class of common stock being registered hereby are not individually named in the table above. Each such unnamed selling stockholder may use this prospectus to resell up to 1% of the class of common stock being registered hereby.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

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

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

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees, donees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of the date that the shares (i) have been sold, pursuant to this prospectus or pursuant to Rule 144, or (ii) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, and without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect. The shares of common stock will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares of common stock covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares of common stock may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to such charter and bylaws and applicable provisions of the DGCL. Copies of our amended and restated certificate of incorporation and amended and restated bylaws are filed as exhibits to the registration statement of which this prospectus is a part.

General

The total number of shares of capital stock which we have authority to issue is 510,000,000 shares. This authorized capital stock consists of 500,000,000 shares of common stock and 10,000,000 shares of preferred stock, each having a par value of $0.0001 per share.

As of August 3, 2026, 61,772,876 shares of our common stock were outstanding and held by 208 stockholders of record.

Common Stock

Our shares of common stock are duly authorized, validly issued, fully paid and non-assessable. Each holder of a share of common stock is entitled to one vote for each share upon all questions presented to the holders of common stock, and the common stock has the exclusive right to vote for the election of directors and for all other purposes (subject to the express terms of the preferred stock). Stockholders do not have preemptive rights or rights to convert their common stock into any other securities.

Stockholders are entitled to receive dividends as may be declared from time to time by the Board out of funds legally available therefor. Stockholders are entitled to share pro rata, upon any liquidation or dissolution, in all remaining assets available for distribution to stockholders after payment or providing for our liabilities and the liquidation preference of any outstanding preferred stock. The rights, preferences and privileges of stockholders are subject to and may be adversely affected by the rights of holders of any series of preferred stock that we may designate and issue at the effective time and in the future.

Our common stock is listed on Nasdaq Capital Market under the symbol “OBX.”

Preferred Stock

Our Charter permits the Board, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series of preferred stock with such designations, powers, preferences, special rights, qualifications, limitations and restrictions as the Board may determine from time to time. Accordingly, without action by the stockholders, the Board may designate and authorize the issuance of additional classes or series of preferred stock having voting rights, dividend rights, conversion rights, redemption provisions and rights in liquidation, dissolution or winding up that are superior to those of common stock.

Charter and Bylaw Provisions; Takeover Statutes

Some provisions of the Delaware law, our restated certificate of incorporation and amended and restated bylaws could make the following transactions more difficult: an acquisition by means of a tender offer; an acquisition by means of a proxy contest or otherwise; or the removal of incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our Company outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Structure of Board

In accordance with the Charter and Bylaws, the Board is divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. The Charter and Bylaws provide that the authorized number of directors may be changed only by resolution of the Board. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of the Board into three classes with staggered three-year terms may delay or prevent a change of management or a change in control of the Company. Directors may be removed only for cause by the affirmative vote of the holders of at least a majority of the shares of stock entitled to vote in the election of the director or directors to be so removed.

Removal of Directors

In accordance with the DGCL and subject to the rights of the holders of any class or series of preferred stock, the entire Board or any individual director may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all of our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on its board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Advance Notice of Proposals and Nominations

The Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The Bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Limits on Special Meetings

The Charter and Bylaws provide that only a majority of the members of the Board then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders.

Amendment of the Bylaws

The Bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth therein; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds

of the outstanding shares of each class entitled to vote thereon as a class, or, if we recommend that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Preferred Stock

Our ability to issue an indeterminate number of shares of the authorized shares of preferred stock with such rights, privileges and preferences as the Board may fix may have the effect of delaying or preventing a takeover or other change of control of the Company.

Takeover Statutes

Section 203 of the DGCL generally prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder who beneficially owns 15% or more of a corporation's voting stock, within three (3) years after the person or entity becomes an interested stockholder, unless: (i) the board of directors of the target corporation has approved, before the acquisition time, either the business combination or the transaction that resulted in the person becoming an interested stockholder, (ii) upon consummation of the transaction that resulted in the person becoming an interested stockholder, the person owns at least 85% of the corporation's voting stock (excluding shares owned by directors who are officers and shares owned by employee stock plans in which participants do not have the right to determine confidentially whether shares will be tendered in a tender or exchange offer) or (iii) after the person or entity becomes an interested stockholder, the business combination is approved by the board of directors and authorized at a meeting of stockholders by the affirmative vote of at least 662⁄3% of the outstanding voting stock not owned by the interested stockholder. Since we did not opt out of the protections of Section 203 of the DGCL, the statute applies to us.

Exclusive Forum

The Bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, or the Charter or Bylaws (including the interpretation, validity or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction or the Securities Act. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, the Bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions,

and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. Investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, the Bylaws provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR HOLDERS OF COMMON STOCK

Material U.S. Federal Income Tax Consequences for Holders of Common Stock

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our shares of common stock, which we refer to as our securities. This discussion applies only to securities that are held as capital assets for U.S. federal income tax purposes and is applicable only to holders who are receiving our securities in this offering.

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors (such as the effects of Section 451 of the Code), including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own 5% or more of our voting shares;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to the securities;
- persons holding the securities as part of a "straddle," hedge, integrated transaction or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships or other pass-through entities for U.S. federal income tax purposes and any beneficial owners of such entities; and
- tax-exempt entities.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and will not seek, a ruling from the Internal Revenue Service, or the IRS, as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our securities through such entities. If a partnership (or other entity or arrangement classified as a

partnership or other pass-through entity for U.S. federal income tax purposes) is the beneficial owner of our securities, the U.S. federal income tax treatment of a partner or member in the partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity. If you are a partner or member of a partnership or other pass-through entity holding our securities, we urge you to consult your tax advisor.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES. EACH PROSPECTIVE INVESTOR IN OUR SECURITIES IS URGED TO CONSULT ITS TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY UNITED STATES FEDERAL NON-INCOME, STATE AND LOCAL, AND NON-U.S. TAX LAWS.

Material U.S. Federal Income Tax Consequences for U.S. Holders

For purposes of this discussion, a "U.S. Holder" is any beneficial owner of our common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Taxation of Distributions. If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder's adjusted tax basis in common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under "*U.S. Holders-Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock*" below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock. Upon a sale or other taxable disposition of common stock, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the common stock. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding

period for the common stock so disposed of exceeds one year. If the holding period requirements are not satisfied, any gain on a sale or taxable disposition of the shares would be subject to short-term capital gain treatment and would be taxed at regular ordinary income tax rates. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its common stock so disposed of. A U.S. holder's adjusted tax basis in its common stock generally will equal the U.S. holder's acquisition cost for the common stock or less, in the case of a share of common stock, any prior distributions treated as a return of capital. In the case of any shares of common stock originally acquired as part of an investment unit, the acquisition cost for the share of common stock that were part of such unit would equal an allocable portion of the acquisition cost of the unit based on the relative fair market values of the components of the unit at the time of acquisition.

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our shares of common stock, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules generally should be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Material U.S. Federal Income Tax Consequences for Non-U.S. Holders

This section applies to you if you are a "Non-U.S. holder." As used herein, the term "Non-U.S. holder" means a beneficial owner of common stock who or that is for U.S. federal income tax purposes:

- a non-resident alien individual (other than certain former citizens and residents of the U.S. subject to U.S. tax as expatriates);
- a foreign corporation; or
- an estate or trust that is not a U.S. holder;

but generally does not include an individual who is present in the United States for 183 days or more in the taxable year of disposition. If you are such an individual, you should consult your tax advisor regarding the U.S. federal income tax consequences of the acquisition, ownership or sale or other disposition of our securities.

Taxation of Distributions. In general, any distributions we make to a Non-U.S. holder of shares of common stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder's adjusted tax basis in its shares of common stock and, to the extent such distribution exceeds the Non-U.S. holder's adjusted tax basis, as gain realized from the sale or other disposition of the common stock, which will be treated as described under "*Non-U.S. Holders-Gain on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock*" below.

The withholding tax does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. income tax as if the Non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A Non-U.S. corporation receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower treaty rate).

Gain on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock. A Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of common stock, unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. holder within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. holder); or
- we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. holder held common stock, and, in the case where shares of common stock are regularly traded on an established securities market, the Non-U.S. holder has owned, directly or constructively, more than 5% of common stock at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. holder's holding period for the shares of common stock. There can be no assurance that common stock will be treated as regularly traded on an established securities market for this purpose.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is a foreign corporation may also be subject to an additional "branch profits tax" at a 30% rate (or lower treaty rate).

If the second bullet point above applies to a Non-U.S. holder, gain recognized by such holder on the sale, exchange or other disposition of common stock will be subject to tax at generally applicable U.S. federal income tax rates.

Information Reporting and Backup Withholding. Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of our shares of common stock. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty will satisfy the certification requirements necessary to avoid the backup withholding as well. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes. Provisions commonly referred to as "FATCA" impose withholding of 30% on payments of dividends (including constructive dividends) on common stock to "foreign financial institutions" (which is broadly defined for this purpose and in general includes investment vehicles) and certain other Non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied by, or an exemption applies to, the payee (typically certified as to by the delivery of a properly completed IRS Form W-8BEN-E). Pursuant to proposed Treasury Regulations, the U.S. Treasury Department has indicated its intent to eliminate the requirement under FATCA of withholding on gross proceeds from the sale or other disposition of property of a type which can produce U.S. source dividends or interest. The U.S. Treasury Department has indicated that taxpayers may rely on these proposed Treasury Regulations pending their finalization. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under certain circumstances, a Non-U.S. holder might be eligible for refunds or credits of such withholding taxes, and a Non-U.S. holder might be required to file a U.S. federal income tax return to claim such refunds or credits. Prospective investors should consult their tax advisers regarding the effects of FATCA on their investment in our securities.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements of Obsidian Therapeutics Sub, Inc. (f/k/a Obsidian Therapeutics, Inc.) as of December 31, 2025 and 2024, and for the years then ended, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The audit report covering the December 31, 2025 consolidated financial statements contains an explanatory paragraph that states that the Company's recurring losses from operations, negative operating cash flows, and accumulated deficit raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and in accordance therewith, file annual, quarterly and current reports, proxy statements and other information with the SEC electronically, and the SEC maintains a website that contains our filings as well as reports, proxy and information statements, and other information issuers file electronically with the SEC at www.sec.gov.

We also make available free of charge on or through our website at *www.obsidiantx.com*, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the SEC. The website addresses are inactive textual references and except as specifically incorporated by reference into this prospectus, information on those websites is not part of this prospectus.

This prospectus and any prospectus supplement are part of a registration statement that we filed with the SEC and do not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Other documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement through the SEC's website, as provided above.

If you would like to request documents, please send a request in writing or by telephone to the following address:

Obsidian Therapeutics, Inc.
1030 Massachusetts Avenue
Cambridge, MA 02138

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS OF OBSIDIAN THERAPEUTICS SUB, INC. (F/K/A OBSIDIAN THERAPEUTICS, INC.)

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Obsidian Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Obsidian Therapeutics, Inc. and subsidiary (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, negative operating cash flows, and has an accumulated deficit, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

We have served as the Company's auditor since 2024.

Boston, Massachusetts
April 22, 2026

OBSIDIAN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(AMOUNTS IN THOUSANDS, EXCEPT FOR SHARE DATA)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 40,405	$ 49,761
Marketable securities	40,081	118,509
Prepaid expenses and other current assets	1,030	4,578
Total current assets	81,516	172,848
Property and equipment, net	1,911	3,322
Right-of-use assets	4,149	6,539
Restricted cash	1,004	1,004
Total assets	$ 88,580	$ 183,713
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 12	$ 1,818
Accrued expenses and other current liabilities	12,291	11,278
Operating lease liabilities, current portion	3,048	2,966
Financing lease liabilities	11	24
Total current liabilities	15,362	16,086
Operating lease liabilities, net of current portion	1,224	3,824
Other non-current liabilities	3	206
Total liabilities	16,589	20,116
Commitments and contingencies (Note 10)		
Redeemable convertible preferred stock; aggregate liquidation preference of $337,001 at December 31, 2025 and 2024	338,028	338,028
Stockholders' deficit:		
Common stock, $0.0001 par value; 274,320,131 shares authorized; 13,941,901 and 13,921,755 shares issued and outstanding as of December 31, 2025 and 2024, respectively	1	1
Additional paid-in-capital	29,874	20,923
Accumulated other comprehensive income (loss)	23	(27)
Accumulated deficit	(295,935)	(195,328)
Total stockholders' deficit	(266,037)	(174,431)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 88,580	$ 183,713

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

OBSIDIAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(AMOUNTS IN THOUSANDS, EXCEPT FOR SHARE AND PER SHARE DATA)

	December 31,	
	2025	2024
Operating expenses:		
Research and development	86,113	73,187
General and administrative	19,554	18,068
Total operating expenses	105,667	91,255
Loss from operations	(105,667)	(91,255)
Other income, net:		
Interest and other income	5,060	8,146
Total other income	5,060	8,146
Loss before income tax expense	(100,607)	(83,109)
Income tax benefit (expense)	—	—
Net loss	$ (100,607)	$ (83,109)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	50	(54)
Total other comprehensive income (loss)	50	(54)
Total comprehensive loss	$ (100,557)	$ (83,163)
Net loss per share attributable to common stockholders, basic and diluted	$ (7.22)	$ (6.47)
Weighted-average common shares outstanding, basic and diluted	13,935,769	12,848,484

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

OBSIDIAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(AMOUNTS IN THOUSANDS, EXCEPT FOR SHARE DATA)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances at December 31, 2023	130,471,047	$178,060	10,877,392	$ 1	$ 11,316	$ 27	$ (112,219)	$ (100,875)
Issuance of common stock upon exercise of stock options	—	—	3,044,363	—	2,547	—	—	2,547
Stock-based compensation	—	—	—	—	7,060	—	—	7,060
Sale of Series C preferred stock, net of issuance costs of $532	84,567,145	159,968	—	—	—	—	—	—
Unrealized gain (loss) on marketable securities	—	—	—	—	—	(54)	—	(54)
Net loss	—	—	—	—	—	—	(83,109)	(83,109)
Balances at December 31, 2024	215,038,192	$338,028	13,921,755	$ 1	$ 20,923	$ (27)	$ (195,328)	$ (174,431)
Issuance of common stock upon exercise of stock options	—	—	20,146	—	20	—	—	20
Stock-based compensation	—	—	—	—	8,931	—	—	8,931
Unrealized gain (loss) on marketable securities	—	—	—	—	—	50	—	50
Net loss	—	—	—	—	—	—	(100,607)	(100,607)
Balances at December 31, 2025	215,038,192	$338,028	13,941,901	$ 1	$ 29,874	$ 23	$ (295,935)	$ (266,037)

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

OBSIDIAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(AMOUNTS IN THOUSANDS)

	Year ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$(100,607)	$ (83,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,484	1,527
Stock-based compensation expense	8,931	7,060
Change in fair value of preferred stock warrant liability	(3)	(8)
Accretion of discount on marketable securities	(2,612)	(2,207)
Non-cash lease expense	(141)	(17)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,548	(2,733)
Accounts payable	(1,806)	701
Accrued expenses and other current liabilities	1,013	3,584
Other non-current liabilities	(200)	200
Net cash used in operating activities	(90,393)	(75,002)
Cash flows from investing activities:		
Purchases of property and equipment	(73)	(779)
Purchases of marketable securities	(80,910)	(131,095)
Maturities of marketable securities	162,000	78,000
Net cash (used in) provided by investing activities	81,017	(53,874)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	20	2,547
Proceeds from Series C financing	—	160,500
Payment of Series C issuance costs	—	(532)
Net cash provided by financing activities	20	162,515
Net decrease in cash and cash equivalents and restricted cash	(9,356)	(33,639)
Cash and cash equivalents and restricted cash at beginning of period	50,765	17,126
Cash and cash equivalents and restricted cash at end of period	$ 41,409	$ 50,765

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

OBSIDIAN THERAPEUTICS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Obsidian Therapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor infiltrating lymphocytes ("TIL") cell therapies for the treatment of patients with solid tumors. The Company's proprietary cytoDRiVE™ platform is highly versatile and allows it to leverage drug responsive domains to control protein function, with its initial focus on TIL cell therapies developed from this platform ("cytoTILs™"). The Company's lead product candidate, OBX-115, is a novel, genetically engineered, autologous TIL cell therapy currently in a Phase 2 clinical trial for the treatment of advanced melanoma and a Phase 1 clinical trial for the treatment of non-small cell lung cancer.

The Company was incorporated in 2015 under the laws of the State of Delaware, and its principal offices are in Cambridge, Massachusetts. Since its inception, the Company has devoted substantially all its efforts to raising capital, obtaining financing, and incurring research and development costs related to advancing its scientific platform.

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Obsidian Therapeutics Securities Corporation. All intercompany balances and transactions have been eliminated.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates currently under development will likely require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance reporting capabilities. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval, or that any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

Going Concern

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for at least one year after the issuance of these consolidated financial statements. As a result of this evaluation, substantial doubt about the Company's ability to continue as a going concern exists.

The Company has a history of operating losses and negative cash flows from operations and expects to continue generating losses as it advances its research and development programs. As of December 31, 2025, the Company had cash, cash equivalents, and marketable securities of $80.5 million and an accumulated deficit of $295.9 million. Net cash used in operating activities was $90.4 million for the year ended December 31, 2025. The Company expects to incur additional losses and negative cash flows from operations over the next several years as the product candidates currently under development will require significant additional research and clinical development efforts prior to commercialization. Based on the Company's accumulated deficit, current and future expected losses, and current cash flow projections, which exclude any new capital raising activities, management determined that the Company does not have adequate financial resources to fund its forecasted operating costs for at least one year after the issuance date of these consolidated financial statements.

Management's plans to alleviate this uncertainty include pursuing additional equity or debt financing, reducing discretionary spending, and exploring strategic collaborations. However, these plans are not fully within the Company's control, and there is no assurance that such funding or arrangements will be available on acceptable terms or at all. Because of the uncertainty inherent in these efforts, the Company has concluded that substantial doubt exists with respect to its ability to continue as a going concern for one year after the issuance date of these consolidated financial statements.

The consolidated financial statements have been prepared assuming the Company will continue operating as a going concern, and no adjustments have been made to the carrying amounts or classification of assets and liabilities that may be necessary if the Company were unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standard Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, and disclosures. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, research and development expenses, fair value of common stock and any resulting equity-based compensation expense, and income taxes. The Company evaluates its estimates and assumptions on an ongoing basis. All revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. Actual results could differ from the Company's estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash with original maturities three months or less at the time of purchase to be cash equivalents. Cash equivalents are stated at fair value.

Marketable Securities

Marketable securities consist of U.S. treasuries with maturities greater than three months. The Company classifies all of its marketable securities as available for sale based upon its intent with regard to such investments. The Company classifies marketable securities as short term when their remaining contractual maturities are one year or less from the balance sheet date, and as long term when the marketable security has a remaining contractual maturity of more than one year from the balance sheet date.

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Dividends are also included in interest and other income.

The Company periodically reviews its investments for impairment based on a security-specific analysis as of each balance sheet date. If the fair value of a security is below its amortized cost, the Company first assesses whether it intends to sell the security or is more likely than not required to sell it before recovery of its amortized

cost. If neither condition is met, the Company evaluates whether a portion of the decline is attributable to credit loss. Any credit-related impairment is recorded as an allowance for credit losses through earnings, with non-credit-related unrealized losses recorded in other comprehensive income (loss). The Company did not recognize any credit loss relating to its investments for the years ended December 31, 2025 or 2024.

Segment Information

The Company manages its operations as a single segment for the purpose of assessing performance and making operating decisions. The Company is developing therapeutic treatments for cancer-related diseases. The Company has determined that its chief operating decision maker is its Chief Executive Officer. The Company's chief operating decision maker reviews the Company's financial information on an aggregated basis for purposes of allocating resources and assessing financial performance. All of the Company's tangible assets are located in the United States and all of the Company's historical collaboration revenue was derived from its collaboration partners headquartered in the United States.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents, and marketable securities. The Company limits its exposure to credit loss by placing its cash with major financial institutions and invests only in short-term obligations. The deposits, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company has no significant off-balance sheet concentrations of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

The Company is dependent on third-party manufacturers to supply certain products for research and development activities in its programs. Certain key raw materials can be difficult to acquire on a consistent basis. If the Company cannot access adequate supply sources its programs could be adversely affected by an interruption in the availability of these raw materials.

Restricted Cash

The Company has restricted cash in the form of letters of credit which are held in interest bearing money market accounts as collateral for the Company's Cambridge, Massachusetts, and Bedford, Massachusetts leases. The Company has classified both money market accounts collateralizing the letters of credit issued as long-term restricted cash on its consolidated balance sheets as the remaining term of each lease exceeds twelve months as of December 21, 2025 and 2024.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Laboratory equipment	5 years
Leasehold improvements	Shorter of the lease term or estimated useful life
Furniture and fixtures	5 years
Computer software	3 years

Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheets and any resulting gains or losses are included in the consolidated statements of operations in the period of disposals.

Impairment of Long-Lived Assets

Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. There were no impairments for the years ended December 31, 2025 or 2024.

Leases

In accordance with ASU 2016-02, *Leases* ("ASC 842"), the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right of use ("ROU") asset and a lease liability on the consolidated balance sheets for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less, and payments are recognized as expense on a straight-line basis over the lease term.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Finance and operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as interest expense using the effective interest method and (ii) a portion that reduces the finance liability associated with the lease.

In addition, the Company examines other contracts with suppliers, vendors and outside parties to identify whether such contracts contain an embedded lease and, as applicable, accounts for such embedded leases in accordance with ASC 842.

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

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

Level 2 - Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's preferred stock warrant liability is carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above. The carrying values of the Company's accounts payable and accrued expenses and other current liabilities approximate their fair value due to the short-term nature of these liabilities.

Redeemable Convertible Preferred Stock

The Company's redeemable convertible preferred stock is classified as temporary equity in the accompanying consolidated balance sheets and excluded from stockholders' deficit as the potential redemption of such stock is outside the Company's control. Costs incurred in connection with the issuance of redeemable convertible preferred stock are recorded as a reduction of gross proceeds from issuance.

The Company did not accrete the carrying values of the preferred stock to the redemption values since the occurrence of either a merger or consolidation; or a sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, of all, or substantially all, of the Company's assets or intellectual property of the Company (a "Deemed Liquidation Event") was not considered probable as of December 31, 2025 or 2024. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that these events will occur. In the event of such a Deemed Liquidation Event, the proceeds from the event are distributed in accordance with the liquidation preferences, provided that the holders of preferred stock have not converted their shares into common stock.

Collaboration Agreements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. When the Company has concluded that a collaborator meets the definition of a customer the Company follows the guidance in ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

Revenue Recognition

Under ASC 606, the Company recognizes revenue associated with collaboration agreements when its customer obtains control of promised goods or services in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation.

The Company assesses the goods or services promised within each contract and determines those that are performance obligations. The Company's collaboration agreements typically consist of promises to transfer licenses to the Company's intellectual property, research and development services, and related supporting activities.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services, including the significance of the Company's integration service, the interdependency of their utility, and the customer's ability to derive their intended benefit from the contract and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the Company's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the customer and the availability of similar services in the general marketplace. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

When an arrangement includes a customer option for additional goods or services, the Company assesses whether the option provides the customer with a material right. A material right is an option to purchase the underlying goods and services at a price below their standalone selling price that the customer would not have received had it not entered into the initial contract. When an option is deemed to provide a material right to the customer, it is accounted for as a separate performance obligation.

The transaction price is the sum of fixed and estimated variable consideration. Variable consideration is estimated using the most likely amount or expected value method to determine the amount of consideration to which the Company expects to be entitled in exchange for transferring the promised goods or services to a customer. The amount of variable consideration included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At each reporting date, the Company re-evaluates the estimate of variable consideration and the constraint.

When arrangements include development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments triggered by events that have significant uncertainty and are not within the Company's control such as regulatory approvals, are not considered probable of being achieved until those approvals are received and are excluded from the transaction price.

For arrangements with licenses of intellectual property, where the license is deemed to be the predominant item to which the royalties relate, the Company utilizes the royalty exception and recognizes revenue and sales-based royalties and milestones at the later of (i) when the related sales occur, or (ii) upon satisfaction of the related performance obligation.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. If the expectation at contract inception is such that the period between the transfer of the promised goods or services to the customer and the payment by the customer will be one year or less, the Company will elect the practical expedient provided by ASC 606 to forego this assessment and conclude a significant financing component does not exist.

Variable consideration may be allocated to a single performance obligation or a subset of distinct goods or services within a series performance obligation if the variable consideration is both earned by the efforts or outcomes of transferring the service and the allocation objective it met. The remaining transaction price is allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception using an approach that maximizes the use of available inputs and may include the adjusted market assessment or cost-plus margin approach. The SSP estimate is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations may require significant judgment, including consideration market conditions, entity-specific pricing strategies, and observable data points on expected costs and profit margins.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the measure of progress that most faithfully depicts our performance towards transferring the related goods and services. The estimate of the Company's measure of progress is updated at each reporting date.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer, a contract liability, which the Company refers to as deferred revenue, is recorded.

Research and Development and Manufacturing Contract Costs and Accruals

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including costs for salaries and bonuses, employee benefits, subcontractors, facility-related expenses, depreciation, stock-based compensation, third-party license fees, laboratory supplies, and external costs of outside vendors engaged to conduct discovery and preclinical development activities as well as to begin to manufacture materials for upcoming clinical trials.

Nonrefundable advance payments for goods or services to be provided in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments under license agreements are expensed as research and development expense upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Contingent milestone payments are recognized when the related contingency is resolved and the amounts are paid or become payable.

The Company has entered into various research, development and manufacturing contracts with research institutions and other companies. These agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research, development and manufacturing costs. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress towards completion of the research, development and manufacturing activities, invoicing to date under the contracts, communication from the research institutions and other companies of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company.

Patent Costs

For the periods ended December 31, 2025 and 2024, costs associated with successful and pending applications of patents and trademarks are recognized as general and administrative expenses as incurred.

Stock-Based Compensation

The Company measures stock-based awards granted to employees, nonemployees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues stock-based awards in the form of stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has also issued stock-based awards in the form of stock options with both performance and service-based vesting conditions. The Company records the expense for stock-based awards with both performance and service-based vesting using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using management's best estimates.

The fair value of each share option is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including:

- *Fair Value of Common Stock* - Because there is no public market for the Company's common shares, the Company has determined the fair value of the Company's common stock based on the independent third-party appraisals. The fair value of the Company's common stock has been determined using a market approach to estimate the Company's enterprise value and applies a hybrid method for allocation of equity value to different classes of equity. The hybrid method is a combination of an option pricing method ("OPM") and a probability-weighted expected return method ("PWERM") that contemplated the Company's financial position and historical financial performance, the status of development of the Company's programs, the current climate in the marketplace, the illiquid nature of the common stock, the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others.
- *Estimated Volatility*—As a private company the Company lacks company-specific historical and implied volatility information for its shares, therefore, the Company estimates its expected share price volatility based on the historical volatility of publicly traded peer companies.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. The Company uses the simplified method to determine the expected term for "plain-vanilla" options, which is based on the average of the time-to-vesting and the contractual life of the options. For awards with both performance and service based vesting conditions, the expected term has been determined using management's best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, and the remaining time-based vesting period, if any. For nonemployees, the Company determines the life to be the contractual term of the option.
- *Risk Free Interest Rate*—The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.
- *Dividend Yield*—The Company has used an expected dividend yield of zero based on the fact that it has never paid cash dividends on its ordinary shares and does not expect to pay any cash dividends in the future.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. As of December 31, 2025 and 2024, the Company had not accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect the Company's stockholders or the Company. The Company assesses the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where the Company has operations to determine the potential effect on its business and any assumptions the Company has made about its future taxable income. The Company cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on its business if they were to be enacted.

Net Loss Per Share

The Company calculated basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities. The Company's
Preferred Stock (as defined below) is considered to be a participating security as the holders are entitled to receive dividends at a dividend rate payable in preference and priority to the holders of common stock. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. There is no allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses of the Company.

Under the two-class method, basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share attributable to common stockholders is computed

by (i) adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities and (ii) dividing the diluted net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For purposes of this calculation, Preferred Stock, preferred stock warrants, and stock options to purchase common stock are considered potential dilutive common shares.

The Company has generated a net loss for each of the periods presented. Accordingly, basic and diluted net loss per share attributable to common stockholders are the same because the inclusion of the potentially dilutive securities would be anti-dilutive.

Other Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. Other comprehensive loss consists of unrealized gains (losses) on marketable securities.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvement to Income Tax Disclosures* ("ASU 2023-09"), to enhance the transparency and decision usefulness of income tax disclosures. ASU 2023-09 became effective for annual periods beginning after December 15, 2024 on a prospective basis for public business entities. For all other entities, the ASU is effective for annual periods beginning after December 15, 2025 on a prospective basis. Early adoption and retrospective application in all prior periods presented is permitted. The Company has early adopted and applied the pronouncement on a retrospective basis. The adoption of ASU 2023-09 did not result in a material impact to the consolidated financial statements and related disclosures.

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires public business entities to disclose specified information about certain costs and expenses on an interim and annual basis. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that adoption of ASU 2024-03 will have on our financial statement disclosures.

3. Financial Instruments and Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following tables present information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair Value Measurements at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$39,905	$ —	$ —	$39,905
U.S. Treasuries	—	40,081	—	40,081
Total assets	$39,905	$40,081	$ —	$79,986
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 3	$ 3
Total liabilities	$ —	$ —	$ 3	$ 3

	Fair Value Measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$49,733	$ —	$ —	$ 49,733
U.S. Treasuries	—	118,509	—	118,509
Total assets	$49,733	$118,509	$ —	$168,242
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 6	$ 6
Total liabilities	$ —	$ —	6	$ 6

Warrants to Purchase Redeemable Convertible Preferred Stock Subject to Conditional Redemption

In connection with the PacificWestern Bank ("PWB") term loan entered into May 2018, the Company granted PWB a warrant to purchase 22,124 shares of Series A-1 preferred stock at an exercise price of $1.1291 per share. The warrant, which was deemed to be classified as a liability, expires on May 25, 2028. The term loan with PWB was fully paid in January 2019 and has since expired. As of December 31, 2025, the warrant has not been exercised.

The fair value of the preferred stock warrant liability is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrant utilized the Black-Scholes option-pricing model, which incorporates a number of assumptions and estimates. Changes in the fair value of the preferred stock warrant are recognized as other income (expense) in the consolidated statements of operations and comprehensive loss and were not material for the years ended December 31, 2025 and 2024.

As of December 31, 2025 and 2024, the estimated fair value of the Series A-1 warrant was $0.13 and $0.28 per share, respectively. The fair value of each warrant share is estimated on the date of grant and at each reporting period using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions including fair value of the underlying preferred stock, estimated volatility, expected term, risk-free interest rate, and expected dividend yield.

The Company assesses its financial liabilities measured at fair value on a recurring basis and transfers its financial liabilities between the relevant fair value hierarchies at the end of each reporting period, as needed. The following table represents a roll-forward of the fair value of the Level 3 preferred stock warrant liability for each of the periods indicated (in thousands):

	As of December 31,	
	2025	2024
Fair value, beginning of year	$ 6	$ 14
Change in estimated fair value	(3)	(8)
Fair value, end of year	$ 3	$ 6

As of December 31, 2025 and 2024 there were no transfers between Level 1, Level 2 and Level 3.

Cash and Cash Equivalents and Marketable Securities

The following tables summarizes the Company's cash, cash equivalents and marketable securities as of December 31, 2025 and 2024 (in thousands):

	Fair Value Measurements at December 31, 2025				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Total
Cash	$ 500	$ —	$ —	$ —	$ 500
Money market funds	39,905	—	—	—	39,905
U.S. Treasuries	40,058	23	—	—	40,081
Total cash, cash equivalents, and marketable securities	$ 80,463	$ 23	$ —	$ —	$80,486
As reported:					
Cash and cash equivalents	$ 40,405	$ —	$ —	$ —	$40,405
Marketable securities	40,058	23	—	—	40,081
	$ 80,463	$ 23	$ —	$ —	$80,486

	Fair Value Measurements at December 31, 2024				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Total
Cash	$ 28	$ —	$ —	$ —	$ 28
Money market funds	49,733	—	—	—	49,733
U.S. Treasuries	118,536	30	(57)	—	118,509
Total cash, cash equivalents, and marketable securities	$168,297	$ 30	$ (57)	$ —	$168,270
As reported:					
Cash and cash equivalents	$ 49,761	$ —	$ —	$ —	$ 49,761
Marketable securities	118,536	30	(57)	—	118,509
	$168,297	$ 30	$ (57)	$ —	$168,270

None of the Company's available-for-sale marketable securities had remaining maturities longer than one year as of December 31, 2025 and 2024.

4. Property and Equipment, Net

Property and equipment, net, are recorded at historical cost and consist of the following (in thousands):

	December 31,	
	2025	2024
Laboratory equipment	$10,017	$ 9,944
Leasehold improvements	261	261
Furniture and fixtures	758	758
Computer software	385	385
Total property and equipment	11,421	11,348
Less: accumulated depreciation	(9,510)	(8,026)
Property and equipment, net	$ 1,911	$ 3,322

Depreciation expense amounted to $1.5 million for each of the years ended December 31, 2025 and 2024.

5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2025	2024
Compensation and benefits	$ 3,830	$ 5,560
External research and development costs	6,361	3,959
Legal and professional fees	685	780
Other	1,415	979
Total accrued expenses and other current liabilities	$ 12,291	$ 11,278

6. Redeemable Convertible Preferred Stock

The Company has issued Series A-1 redeemable convertible preferred stock (the "Series A-1 Preferred Stock"), Series A-2 redeemable convertible preferred stock (the "Series A-2 Preferred Stock"), Series A-3 redeemable convertible preferred stock, (the "Series A-3 Preferred Stock"), Series B redeemable convertible preferred stock (the "Series B Preferred Stock") and Series C redeemable convertible preferred stock (the "Series C Preferred Stock"); collectively referred to as the "Preferred Stock" and the holders of the Preferred Stock as the "Preferred Stockholders." All series of Preferred Stock have a par value of $0.0001.

In March 2024, the Company entered into a stock purchase agreement (the "Series C Purchase Agreement") pursuant to which the Company issued and sold an aggregate of 84,567,145 shares of Series C Preferred Stock at a price of $1.8979 per share, for gross proceeds of approximately $160.5 million and incurred issuance costs of $0.5 million.

Upon issuance of each class of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance dates of each class of Preferred Stock.

At December 31, 2025 and 2024, the Preferred Stock is summarized below (in thousands, except share amounts):

	Amounts at December 31, 2025 and December 31, 2024				
	Total Shares Authorized	Total Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Shares Issuable Upon Conversion
Series A-1 Preferred Stock	33,222,339	33,200,215	$ 37,486	$ 37,486	33,200,215
Series A-2 Preferred Stock	14,936,323	14,936,323	16,807	14,936	14,936,323
Series A-3 Preferred Stock	6,146,592	6,146,592	9,035	9,035	6,146,592
Series B Preferred Stock	76,187,917	76,187,917	114,732	115,044	76,187,917
Series C Preferred Stock	84,567,145	84,567,145	159,968	160,500	84,567,145
Total	215,060,316	215,038,192	$ 338,028	$ 337,001	215,038,192

The rights and preferences of the Preferred Stock are as follows:

Voting Rights

The Preferred Stockholders vote on an as-converted basis with holders of common stock on all general matters. Additionally, holders of Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock each have the exclusive right to elect one director per series, voting separately as a class. Holders of Series

A-3 Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock also hold series-specific protective voting rights requiring their separate approval for certain amendments or capital structure actions, and all Preferred Stockholders voting together as a single class (with a required majority of holders of Series C Preferred Stock included) must approve major corporate actions such as liquidation events, charter amendments affecting rights of Preferred Stockholders, creation of senior or junior securities, certain indebtedness, and other key matters.

Dividend Rights

The Preferred Stockholders are entitled to receive, prior to the payment of any dividend on the common stock, a dividend on each outstanding share of preferred stock on an as converted to common stock basis immediately prior to the record date. Any such dividends shall be payable only when, as, and if declared by the Company's board of directors. No dividends have been declared through December 31, 2025.

Liquidation Preference

The Series C Preferred Stock ranks senior to the Series B Preferred Stock, Series A Preferred Stock and Common Stock of the Company. In the event of a liquidation of the Company, or certain deemed liquidation events, the Series C is redeemable for a price equal to the greater of (i) Series C Original Issue Price of $1.8979 per share, plus any dividends declared but unpaid, or (ii) such amount per share as would have been payable had all Series C Preferred Stock converted into common stock immediately prior to the liquidation or deemed liquidation. If assets or surplus remain after satisfying the Series C Preferred Stockholders, the Series B Preferred Stock is redeemable for a price equal to the greater of (i) Series B Original Issue Price of $1.51 per share, plus any dividends declared but unpaid, or (ii) such amount per share as would have been payable had all Series B Preferred Stock converted into common stock immediately prior to the liquidation or deemed liquidation. If assets or surplus remain after satisfying the Series B Preferred Stockholders, the Series A Preferred Stockholders is redeemable for a price equal to the greater of (i) Series A-1, Series A-2, and Series A-3 Original Issue Price of $1.1291, $1.00, and $1.47 per share, respectively, plus any dividends declared but unpaid, or (ii) such amount per share as would have been payable had all Series A-1, A-2 and A-3 Preferred Stock converted into common stock immediately prior to the liquidation or deemed liquidation.

In the event of a liquidation event or deemed liquidation, if the assets or surplus funds to be distributed to the holders of Series C Preferred Stock, are insufficient to permit the payment to such holders of their full aggregate distribution due, the assets and surplus legally available for distribution shall be distributed ratably among the holders of Series C Preferred Stock in proportion to the full aggregate Series C distributions each such holder is otherwise entitled to receive. After distribution to Series C Preferred Stockholders the same distribution would take place to Series B Preferred Stockholders if any assets or surplus remain. After distribution to Series B Preferred Stockholders the same distribution would take place to Series A Preferred Stockholders if any assets or surplus remain. No payment shall be made with respect to the common stock unless and until full payment has been made to the holders of the Series C Preferred Stock, Series B Preferred Stock and Series A Preferred Stock of the distribution amounts that they are entitled to receive.

Redemption Rights

The Preferred Stockholders do not have redemption rights, except upon a Deemed Liquidation Event.

Conversion

Optional Conversion

Each share of Preferred Stock, at the option of the holder, is convertible into a number of fully paid shares of common stock as determined by dividing issue price by the conversion price in effect at the time. The initial conversion price per share for Series A-1, Series A-2 and Series A-3 Preferred Stock is $1.1291, $1.00, and

$1.47, respectively, the Series B Preferred Stock initial conversion price is $1.51 per share and the Series C Preferred Stock initial conversion price if $1.8979. Such initial conversion prices, and the rate at which shares of Preferred Stock may be converted into shares of common stock, shall be subject to adjustment as provided in the Company's fourth amended and restated certificate of incorporation.

Mandatory Conversion

All outstanding shares of Preferred Stock will automatically convert into a number of fully paid shares of common stock at the then applicable conversion price upon the completion of either (i) the closing of the sale of shares of common stock to the public in a sale price of at least $2.8469 per share resulting in gross proceeds to the Company of at least $100.0 million ("Qualified IPO") or; (ii) the direct listing on a nationally recognized stock exchange with a reference price of at least $2.8469 per share or; (iii) a special purpose acquisition company ("SPAC") transaction or reverse merger transaction resulting in a sale price of at least $2.8469 per share or; (iv) other event that results in the Company or its successor in interest having its common equity listed for trading on a nationally recognized stock exchange with a share price of at least $2.8469 per share or upon the vote or written consent of a majority of holders of the then outstanding shares of Preferred Stock voting together as a single class on an as-converted to common stock basis.

7. Common Stock

The Company's fourth amended and restated certificate of incorporation authorizes the authorizes the Company to issue 274,320,131 shares of common stock. As of December 31, 2025, the Company had reserved 215,060,316 shares of common stock for the conversion of the Preferred Stock (Note 6), as applicable.

The holders of shares of common stock are entitled to one vote for each share held with respect to all matters voted on by the stockholders of the Company. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. In a Deemed Liquidation Event, after the payment in full of all preferential amounts required to be paid to the holder of shares of Preferred Stock, the holders of the then outstanding common stock are entitled to receive that portion of the remaining funds to be distributed to holders of common stock.

8. Stock-Based Compensation

2016 Equity Incentive Plan

In March 2016, the Company adopted the 2016 Stock Option and Grant Plan (the "2016 Plan"), which allows the granting of awards in the form of incentive stock options, nonqualified stock options, and stock grants, which may include restricted stock, to eligible employees, outside directors and consultants of the Company. The total number of common stock reserved for grant under the 2016 Plan was 48,749,161 shares as of December 31, 2025 and December 31, 2024, of which 4,475,263 and 1,993,987 shares remained available for future issuance as of December 31, 2025 and 2024, respectively. Shares that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards under the 2016 Plan.

The 2016 Plan is administered by the Company's board of directors. The terms of stock awards agreements, including type of stock award to be granted, the provisions of each stock award, including the number of shares, vesting requirements, and exercise prices, are determined by the board of directors, and are subject to the provisions of the 2016 Plan. Option awards generally vest over a four-year period and expire after ten years. Certain options provide for accelerated vesting in the event of a change in control, as defined. The exercise price per share for stock options granted may not be less than the fair market value of the common stock at the date of grant.

Stock Options

The Company has granted stock options with service-based vesting conditions, performance-based, and with both service and performance-based vesting conditions. The Company typically grants stock options to employees and nonemployees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant. Stock options typically vest over four years and have a maximum term of ten years.

The Company estimates the fair value of the stock options issued using the Black-Scholes option pricing model on the date of grant. The key assumptions used to apply this pricing model were as follows:

	December 31,	
	2025	2024
Fair value of common stock	$0.78 – 1.13	$1.01 – 1.13
Risk-free interest rate	3.94%	4.25%
Expected dividend yield	—	—
Expected term (in years)	6.1	6.1
Expected volatility	89.54%	133.20%

The weighted average fair value of options granted during the years ended December 31, 2025 and 2024 was $0.62 and $1.03, respectively.

The following table summarizes option activity under the 2016 Plan for the year ended December 31, 2025:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	40,628,032	$ 1.03	8.4	$ 4,146
Options granted	432,000	0.78		
Options exercised	(20,146)	0.97		
Options forfeited	(2,530,814)	1.05		
Options expired	(447,462)	1.00		
Outstanding at December 31, 2025	38,061,610	$ 0.77	6.9	$ 298
Vested and exercisable at December 31, 2025	23,056,967	$ 0.77	6.1	$ 298
Unvested at December 31, 2025	15,004,643	$ 0.78	8.2	$ —

Included within the total stock options outstanding at December 31, 2025, are 2,027,700 stock options to purchase common stock which have either both performance and service-based vesting criteria or performance only vesting criteria (collectively, the “Performance Awards”) and were granted to certain employees and officers during 2023 and 2024. Of the total 2,027,700 Performance Awards outstanding: (i) 1,231,034 outstanding stock options were granted in 2023 and had performance criteria tied to the achievement of three scientific milestones, each followed by two years of service vesting. Expense was recognized when achievement became probable. As of December 31, 2025, all three milestones associated with this grant had either been achieved or partially achieved; (ii) 442,592 outstanding stock options were granted in 2023 and had performance criteria tied to the completion of a strategic transaction, which was achieved upon the close of the Series C Preferred Stock financing in March 2024, and therefore the grant date fair value of the stock options was expensed in full upon achievement of the financing; and (iii) 354,074 outstanding stock options were granted in 2024 and had performance criteria tied to the achievement of strategic milestones of the Company along with service-based vesting conditions. As of December 31, 2025, the performance milestones have not yet been achieved and are not deemed probable of being achieved. Total stock-based compensation expense associated with performance stock options was $0.2 million and $0.7 million during the years ended December 31, 2025 and 2024, respectively.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

The aggregate intrinsic value of options exercised for each of the years ended December 31, 2025 and 2024 totaled zero and $0.8 million, respectively. As of December 31, 2025 there was $13.3 million of unrecognized compensation expense, which the Company expects to recognize over a weighted-average period of 2.03 years.

The Company has recorded stock-based compensation expense as follows (in thousands):

	December 31,	
	2025	2024
Research and development	$3,733	$2,938
General and administrative	5,198	4,122
	$8,931	$7,060

9. Income Taxes

For the years ended December 31, 2025 and 2024, no income tax expense was recorded due to the Company's net operating loss ("NOL") and full valuation allowance. The Company has historically incurred net operating losses and maintains a full valuation allowance against its deferred tax assets.

All of the Company's operating losses since inception have been generated in the United States.

The reported amount of income tax expense for the years differs from the amount that would result from applying domestic federal statutory rates to pretax losses primarily because of changes in the valuation allowance.

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,			
	2025		2024	
	Amount (in thousands)	Rate	Amount (in thousands)	Rate
Federal statutory income tax rate	(21,127)	21.00%	(17,523)	21.00%
Permanent difference	777	(0.77)%	644	(0.77)%
State taxes, net of federal benefit	73	(0.07)%	(123)	0.15%
Research and development credits	(3,781)	3.76%	(4,999)	5.99%
Change in valuation allowance	24,058	(23.91)%	22,002	(26.37)%
Effective income tax rate	—	0.00%	—	0.00%

In 2025 and 2024, state and local income taxes in Massachusetts comprised the majority of the state and local income taxes, net of federal benefit category.

Net deferred tax assets (liabilities) as of December 31, 2025 and 2024 consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets		
Net operating loss carryforwards	$ 49,893	$ 17,753
Research and development tax credit carryforwards	23,251	18,430
Lease right-of-use liability	1,794	1,800
Accrued expenses and other liabilities	885	1,352
Stock Compensation Expense	2,815	2,192
IRC 174 capitalized research and development	19,836	27,129
Other	1,202	662
Total deferred tax assets	99,676	69,319
Less: Valuation allowance	(98,055)	(67,584)
Net deferred tax assets	1,621	1,735
Deferred tax liabilities		
Lease right-of-use asset	(1,728)	(1,734)
Depreciation	107	(1)
Total deferred tax liabilities	(1,621)	(1,735)
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2025 and 2024, the Company had federal NOL carryforwards of $186.5 million and $66.2 million, respectively, and state NOL carryforwards of $171.0 million and $61.2 million, respectively, which may be available to offset future taxable income. Federal NOL carryforwards do not expire and state NOLs begin to expire in 2037.

As of December 31, 2025 and 2024, the Company also had federal research and development tax credit carryforwards of $17.1 million and $13.3 million, respectively, and state research and development credit carryforwards of $7.7 million and $6.5 million, respectively, which may be available to offset future income tax liabilities. Federal and state research and development tax credit carryforwards begin to expire in 2037 and 2031, respectively.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has completed an evaluation of ownership changes through December 31, 2022 to assess whether utilization of the Company's net operating loss or research and development credit carryforwards would be subject to an annual limitation under Section 382, and it was determined that an ownership change has occurred. The Company has determined that no attributes will expire unused, as of December 31, 2022, based on the limitation analysis. To the extent a subsequent ownership change occurs, the net operating loss and credit carryforwards may be subject to additional limitation.

The Company has not yet conducted a study of its research and development credit carryforwards. This study may result in an increase or decrease to the Company's credit carryforwards, however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. As a result, there would be no impact to the consolidated statements of operations and comprehensive loss or consolidated statements of cash flows if an adjustment were required.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development credit carryforwards. Management has considered the Company's history of net losses incurred since inception and its lack of commercialization of any products or generation of revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2025 and 2024. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2025 and 2024 related primarily to the increase in net operating loss carryforwards and were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Valuation allowance at the beginning of the year	$ 67,584	$ 40,458
Increases recorded to income tax provision	30,471	27,126
Valuation allowance at end of the year	$ 98,055	$ 67,584

The increase in the valuation allowance of $30.5 million during the year ended December 31, 2025 related primarily to the increase in net operating loss carryforwards.

The Company assesses the uncertainty in its income tax positions to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For the tax position meeting the more-likely-than-not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than 50% likelihood of being realized upon the ultimate settlement with the relevant taxing authority. As of December 31, 2025 and 2024, the Company had not recorded any reserves for uncertain tax positions or related interest and penalties.

The Company files income tax returns as prescribed by the tax law of the jurisdiction in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdiction, where applicable. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state, and local income tax authorities for all tax years in which a loss carryforward is available.

10. Commitments and Contingencies

401(k) Plan

In January 2017, and as amended in February 2020, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Starting in 2020, the Company makes matching contributions at a rate of 100% of each employee's contribution up to a maximum employee contribution of 3% of eligible plan compensation. For each of the years ended December 31, 2025 and 2024, the Company made matching contributions of $0.5 million.

Other Contractual Obligations

The Company enters into contracts in the normal course of business with third parties for preclinical research studies, upcoming clinical trials and testing and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by the Company upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of the service providers, up to the date of cancellation and in the case of certain arrangements may include noncancelable fees.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal Proceedings

The Company is not a party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of losses is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

Collaboration and License Agreement with University of Texas M.D. Anderson Cancer Center

In November 2020, the Company entered into a multi-year collaborative research and option agreement (the "Collaboration Agreement") with the Board of Regents (the "Board of Regents") of The University of Texas System, on behalf of the University of Texas M.D. Anderson Cancer Center ("M.D. Anderson") designed to expedite the research and development of novel engineered TIL for the treatment of solid tumors. Pursuant to the Collaboration Agreement, as amended, the Company agreed to fund research activities of up to $8.3 million over approximately two years and received the option to obtain a license to certain intellectual property arising from the collaboration. The collaboration focused on developing TIL containing regulated membrane-bound IL15 ("mbIL15") with the potential to enhance anti-tumor efficacy and reduce tumor burden in patients suffering from different types of solid tumors. The collaboration's purpose was to accelerate the development of cytoTIL, including process and analytical development and clinical readiness activities. The Collaboration Agreement expired in 2023 and, prior to such expiration, the Company exercised its option to license certain intellectual property arising from the collaboration and subsequently entered into the resulting license agreement with the Board of Regents on behalf of M.D. Anderson ("M.D. Anderson License Agreement") in October 2021.

Under the M.D. Anderson License Agreement, the Company is obligated to pay to M.D. Anderson (a) a royalty on net sales of Developed Products and licensed products at a low single digit percentage (b) milestone payments of up to (i) $75.0 million upon the achievement of certain specified clinical and regulatory milestones and (ii) $90.0 million upon the achievement of certain specified sales milestones, which milestones may be payable with respect to multiple products and indications and (c) a share of certain consideration received by the Company from sublicensees under any sublicense agreements with third parties. As of December 31, 2025, no additional milestone payments were considered probable of achievement and, accordingly, no related liability has been recognized.

The M.D. Anderson License Agreement may be terminated by the Board of Regents upon notice for an uncured challenge of the Board of Regents' patents and by mutual agreement of us and the Board of Regents.

11. Leases

The Company leases laboratory and office space in Cambridge, Massachusetts under an operating lease with a term expiring in January 2027.

Additionally, the Company leases office space in Bedford, Massachusetts under an operating lease with a term expiring in December 2028. During the year ended December 31, 2025, and 2024, the components of operating lease cost were as follows, and are reflected in general and administrative expenses and research and development expenses, as determined by the underlying activities (in thousands):

	December 31,	
	2025	2024
Lease cost		
Operating lease cost	$2,757	$2,757
Variable operating lease cost	541	516
Total operating lease cost	$3,298	$3,273

The following table summarizes information related to the measurement of the Company's operating leases for the years ended December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Weighted-average remaining lease term (years)	1.90	2.80
Weighted-average discount rate	6.82%	7.13%
Cash paid for amounts included in the measurement of operating lease liabilities	$2,896	$2,776

Maturities of the Company's operating lease liabilities at December 31, 2025 are as follows (in thousands):

2026	$2,976
2027	855
2028	673
Total minimum lease payments	4,504
Less: Interest portion	(232)
Total present value of operating lease liabilities	$4,272

12. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (100,607)	$ (83,109)
Denominator		
Weighted-average common shares outstanding, basic and diluted	13,935,769	12,848,484
Net loss per share attributable to common stockholders, basic and diluted	$ (7.22)	$ (6.47)

The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders' during the year ended December 31, 2025, and 2024 because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Redeemable convertible preferred stock	215,038,192	215,038,192
Warrants to purchase Series A-1 redeemable convertible preferred stock	22,124	22,124
Options to purchase common stock	38,061,610	40,628,032
Total	253,121,926	255,688,348

13. Related Party Transactions

The Company entered into individual collaboration and license agreements with Celgene Corporation ("Celgene") in 2019 and 2020, respectively, and a collaboration agreement with Vertex Pharmaceuticals, Inc. ("Vertex") in 2021. Both Celgene and Vertex purchased the Company's Preferred Stock in connection with the collaboration agreements. All performance obligations under the collaboration agreements were satisfied in previous reporting periods. Accordingly, during the years ended December 31, 2025 and 2024, the Company did not recognize related party revenue associated with the collaboration agreements. The Celgene collaboration agreement was terminated in October 2025 and the Celgene license agreement was terminated in November 2025. The Vertex collaboration agreement expired in April 2025. No future revenue associated with these collaboration arrangements will be recognized.

14. Segment Information

The Company operates and manages its business as a single segment, focused on developing engineered cell and gene therapies to deliver transformative outcomes for patients. The Company's cytoDRiVE® technology is designed to precisely regulate the timing and level of protein function by using FDA-approved small molecule drugs. The Company's lead investigational cytoTIL15™ program, amsoki-cel, is a novel engineered tumor-derived autologous T cell immunotherapy, with the potential to become a treatment option for metastatic melanoma and other solid tumors.

The determination of a single reporting and operating segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's Chief Executive Officer ("CEO"), as the CODM, uses consolidated, single-segment financial information for purposes of evaluating performance, making operating decisions, allocating resources, and planning and forecasting for future periods. The CODM assesses performance and decides how to allocate resources based on consolidated net income (loss). This measure is used to monitor budget versus actual results to evaluate the performance of the segment. The CODM reviews cash, cash equivalents and marketable securities as a measure of segment assets. As of December 31, 2025 and 2024, the Company's cash, cash equivalents and marketable securities were $80.5 million and $168.3 million, respectively.

The following tables illustrate information about segment revenue, significant segment expenses and segment operating loss for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Revenues:	$ —	$ —
Less(1):		
Research and development expenses(2):		
Compensation and related expenses	21,828	24,537
Drug discovery and platform	1,026	844
Clinical and manufacturing activities	52,065	36,831
Occupancy and all other costs	7,461	8,037
Total research and development expense	$ 82,380	$ 70,249
General and administrative expenses(3):		
Compensation and related expenses	8,174	7,912
Consulting and professional services	4,382	4,791
Occupancy and all other costs	1,800	1,243
Total general and administrative expense	$ 14,356	$ 13,946
Stock-based compensation	8,931	7,060
Other segment items(4)	(5,060)	(8,146)
Net loss	$(100,607)	$(83,109)

(1) The significant expense categories and amounts align with the segment-level information that is regularly provided to the chief operating decision maker.
(2) Research and development expense for the years ended December 31, 2025 and 2024 exclude $3.7 million and $2.9 million of stock-based compensation expense, respectively, which is presented separately below.
(3) General & administrative expense for the years ended December 31, 2025 and 2024 exclude $5.2 million and $4.1 million of stock-based compensation expense, respectively, which is presented separately below.
(4) Other segment items include interest and other income, net.

15. Subsequent Events

The Company has evaluated subsequent events through April 22, 2026, the date these consolidated financial statements were issued, and determined that there have been no events that have occurred that would require adjustments to the Company's disclosures in the consolidated financial statements, except for the following:

Conversion of Series A-1 Preferred Stock

In February 2026, a holder of the Company's Series A-1 Preferred Stock delivered a notice electing to convert 7,085,290 shares of its Series A-1 Preferred Stock into an equivalent number of shares of the Company's common stock on a one-for-one basis, in accordance with the conversion provisions of the Company's fourth amended and restated certificate of incorporation. The conversion was effective upon the Company's receipt of the notice and was not subject to any conditions. Following the conversion, 7,085,290 shares of Series A-1 Preferred Stock were cancelled, and an equal number of common shares were issued to such holder.

SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA OF LEGACY OBSIDIAN

OBSIDIAN THERAPEUTICS SUB, INC. (F/K/A OBSIDIAN THERAPEUTICS, INC.)
CONDENSED CONSOLIDATED BALANCE SHEETS
(AMOUNTS IN THOUSANDS, EXCEPT FOR SHARE DATA)
(UNAUDITED)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 17,983	$ 40,405
Marketable securities	16,462	40,081
Prepaid expenses and other current assets	11,914	1,030
Total current assets	46,359	81,516
Property and equipment, net	1,201	1,911
Right-of-use assets	2,878	4,149
Restricted cash	1,004	1,004
Total assets	$ 51,442	$ 88,580
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 365	$ 12
Accrued expenses and other current liabilities	17,853	12,291
Operating lease liabilities, current portion	1,974	3,048
Financing lease liabilities	4	11
Total current liabilities	20,196	15,362
Operating lease liabilities, net of current portion	928	1,224
Other non-current liabilities	1	3
Total liabilities	21,125	16,589
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock; aggregate liquidation preference of $329,001 and $337,001 at June 30, 2026 and December 31, 2025, respectively	330,028	338,028
Stockholders' deficit:		
Common stock, $0.0001 par value; 274,320,131 shares authorized; 22,188,335 and 13,941,901 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	2	1
Additional paid-in-capital	41,722	29,874
Accumulated other comprehensive income (loss)	(3)	23
Accumulated deficit	(341,432)	(295,935)
Total stockholders' deficit	(299,711)	(266,037)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 51,442	$ 88,580

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

OBSIDIAN THERAPEUTICS SUB, INC. (F/K/A OBSIDIAN THERAPEUTICS, INC.)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(AMOUNTS IN THOUSANDS, EXCEPT FOR SHARE AND PER SHARE DATA)
(UNAUDITED)

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	21,549	22,952	37,281	44,078
General and administrative	4,591	5,307	9,139	10,784
Total operating expenses	26,140	28,259	46,420	54,862
Loss from operations	(26,140)	(28,259)	(46,420)	(54,862)
Other income, net:				
Interest and other income	276	1,363	923	2,980
Total other income	276	1,363	923	2,980
Loss before income tax expense	(25,864)	(26,896)	(45,497)	(51,882)
Income tax benefit (expense)	—	—	—	—
Net loss	$ (25,864)	$ (26,896)	$ (45,497)	$ (51,882)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	2	(11)	(26)	(11)
Total other comprehensive income (loss)	2	(11)	(26)	(11)
Total comprehensive loss	$ (25,862)	$ (26,907)	$ (45,523)	$ (51,893)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.19)	$ (1.93)	$ (2.30)	$ (3.72)
Weighted-average common shares outstanding, basic and diluted	21,808,064	13,939,366	19,751,933	13,931,419

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

OBSIDIAN THERAPEUTICS SUB, INC. (F/K/A OBSIDIAN THERAPEUTICS, INC.)
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(AMOUNTS IN THOUSANDS, EXCEPT FOR SHARE DATA)
(UNAUDITED)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances at December 31, 2025	215,038,192	$338,028	13,941,901	$ 1	$ 29,874	$ 23	$ (295,935)	$ (266,037)
Issuance of common stock upon exercise of stock options	—	—	59,937	—	47	—	—	47
Stock-based compensation	—	—	—	—	1,454	—	—	1,454
Conversion of Series A Preferred Stock	(7,085,290)	(8,000)	7,085,290	1	7,999	—	—	8,000
Unrealized gain (loss) on marketable securities	—	—	—	—	—	(28)	—	(28)
Net loss	—	—	—	—	—	—	(19,633)	(19,633)
Balances at March 31, 2026	207,952,902	$330,028	21,087,128	$ 2	$ 39,374	$ (5)	$ (315,568)	(276,197)
Issuance of common stock upon exercise of stock options	—	—	1,101,207	—	796	—	—	796
Stock-based compensation	—	—	—	—	1,552	—	—	1,552
Unrealized gain (loss) on marketable securities	—	—	—	—	—	2	—	2
Net loss	—	—	—	—	—	—	(25,864)	(25,864)
Balances at June 30, 2026	207,952,902	$330,028	22,188,335	$ 2	$ 41,722	$ (3)	$ (341,432)	$ (299,711)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances at December 31, 2024	215,038,192	$338,028	13,921,755	$ 1	$ 20,923	$ (27)	$ (195,328)	$ (174,431)
Issuance of common stock upon exercise of stock options	—	—	17,611	—	6	—	—	6
Stock-based compensation	—	—	—	—	2,110	—	—	2,110
Net loss	—	—	—	—	—	—	(24,986)	(24,986)
Balances at March 31, 2025	215,038,192	$338,028	13,939,366	$ 1	$ 23,039	$ (27)	$ (220,314)	$ (197,301)
Issuance of common stock upon exercise of stock options	—	—	—	—	12	—	—	12
Stock-based compensation	—	—	—	—	2,761	—	—	2,761
Unrealized gain (loss) on marketable securities	—	—	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	—	—	(26,896)	(26,896)
Balances at June 30, 2025	215,038,192	$338,028	13,939,366	$ 1	$ 25,812	$ (38)	$ (247,210)	$ (221,435)

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

OBSIDIAN THERAPEUTICS SUB, INC. (F/K/A OBSIDIAN THERAPEUTICS, INC.)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(AMOUNTS IN THOUSANDS)
(UNAUDITED)

	Six months ended June 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$(45,497)	$(51,882)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	635	752
Stock-based compensation expense	3,006	4,871
Change in fair value of preferred stock warrant liability	(2)	2
Accretion of discount on marketable securities	(407)	(1,621)
Loss on sale of property and equipment	56	—
Non-cash lease expense	(106)	(67)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(10,884)	3,370
Accounts payable	353	(1,339)
Accrued expenses and other current liabilities	5,562	250
Other non-current liabilities	—	(200)
Net cash used in operating activities	(47,284)	(45,864)
Cash flows from investing activities:		
Purchases of property and equipment	—	(57)
Purchases of marketable securities	—	(36,192)
Maturities of marketable securities	24,000	67,000
Proceeds from the sale of property and equipment	19	—
Net cash provided by investing activities	24,019	30,751
Cash flows from financing activities:		
Proceeds from the exercise of stock options	843	18
Net cash provided by financing activities	843	18
Net decrease in cash and cash equivalents and restricted cash	(22,422)	(15,095)
Cash and cash equivalents and restricted cash at beginning of period	41,409	50,765
Cash and cash equivalents and restricted cash at end of period	$ 18,987	$ 35,670

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

OBSIDIAN THERAPEUTICS SUB, INC. (F/K/A OBSIDIAN THERAPEUTICS, INC.)
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of the Business and Basis of Presentation

Obsidian Therapeutics Sub, Inc. (formerly known as, Obsidian Therapeutics, Inc.) (the "Company" is a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor infiltrating lymphocytes ("TIL") cell therapies for the treatment of patients with solid tumors. The Company's proprietary cytoDRiVE™ platform is highly versatile and allows it to leverage drug responsive domains to control protein function, with its initial focus on TIL cell therapies developed from this platform ("cytoTILs™"). The Company's lead product candidate, OBX-115, is a novel, genetically engineered, autologous TIL cell therapy currently in a Phase 2 clinical trial for the treatment of advanced melanoma and a Phase 1 clinical trial for the treatment of non-small cell lung cancer.

The Company was incorporated in 2015 under the laws of the State of Delaware, and its principal offices are in Cambridge, Massachusetts. Since its inception, the Company has devoted substantially all its efforts to raising capital, obtaining financing, and incurring research and development costs related to advancing its scientific platform.

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Obsidian Therapeutics Securities Corporation. All intercompany balances and transactions have been eliminated.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates currently under development will likely require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance reporting capabilities. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval, or that any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

Liquidity

The Company has a history of operating losses and negative cash flows from operations and expects to continue generating losses as it advances its research and development programs. As of June 30, 2026 the Company had cash, cash equivalents, and marketable securities of $34.4 million.

On April 14, 2026, the Company entered into a definitive merger agreement with Galera Therapeutics, Inc. ("Galera") pursuant to which both companies were to become wholly owned subsidiaries of a newly formed holding company, Gazelle Parent, Inc. ("Gazelle"). In connection with the merger, Gazelle, the Company and Galera secured commitments for a private investment in public equity financing in Galera with expected gross proceeds of approximately $350.0 million.

On July 31, 2026, immediately prior to the completion of the merger transaction and before the issuance of these condensed consolidated financial statements, the Concurrent PIPE Financing (as defined below) closed and

generated gross proceeds of approximately $350.0 million. The Company expects that its cash, cash equivalents and marketable securities subsequent to the closing of the Concurrent PIPE Financing will be sufficient to fund its operating expenses and capital expenditure requirements through the next twelve months from the date of issuance of these condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). In our opinion, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported interim periods. We consider events or transactions that occur after the balance sheet date but before the condensed consolidated financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements, including the related notes thereto, for the year ended December 31, 2025.

There were no changes to the Company's significant accounting policies during the six months ended June 30, 2026, other than noted below.

Deferred Offering Costs

The Company capitalizes legal, accounting, and other professional fees directly related to the Concurrent PIPE Financing (as defined below) and merger, which are recorded within prepaid expenses and other current assets on the condensed consolidated balance sheets and are expensed or charged against additional paid-in capital, as applicable, upon closing of the merger transaction and Concurrent PIPE Financing.

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, or ASU 2024-03*,* which requires public business entities to disclose specified information about certain costs and expenses on an interim and annual basis. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. Obsidian Sub is currently evaluating the impact that adoption of ASU 2024-03 will have on its consolidated financial statements and related disclosures.

In December 2025, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2025-12, Codification Improvements, which includes amendments to Accounting Standards Codification, or ASC, 260, Earnings Per Share. The amendments clarify guidance related to the calculation of diluted earnings per share when an entity reports a loss from continuing operations, including the evaluation of the effect of potential common shares. ASU 2025-12 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual periods, and are required to be applied retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2025-12 on its consolidated financial statements and related disclosures.

3. Financial Instruments and Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following tables present information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair Value Measurements at June 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$17,733	$ —	$ —	$17,733
U.S. Treasuries	—	16,462	—	$16,462
Total assets	$17,733	$16,462	$ —	$34,195
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 1	$ 1
Total liabilities	$ —	$ —	$ 1	$ 1

	Fair Value Measurements at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$39,905	$ —	$ —	$39,905
U.S. Treasuries	—	40,081	—	40,081
Total assets	$39,905	$40,081	$ —	$79,986
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 3	$ 3
Total liabilities	$ —	$ —	$ 3	$ 3

There were no transfers between Level 1, Level 2 and Level 3 categories during the three and six months ended June 30, 2026.

Warrants to Purchase Redeemable Convertible Preferred Stock Subject to Conditional Redemption

There were no material changes to the terms, classification, or accounting for the Company's warrants to purchase redeemable convertible preferred stock subject to conditional redemption during the three and six months ended June 30, 2026.

Cash and Cash Equivalents and Marketable Securities

The following tables summarizes the Company's cash, cash equivalents and marketable securities as of June 30, 2026 and December 31, 2025 (in thousands):

	Fair Value Measurements at June 30, 2026				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Total
Cash and cash equivalents	$ 17,983	$ —	$ —	$ —	$17,983
U.S. Treasuries	16,465	$ —	(3)	—	16,462
Total cash, cash equivalents, and marketable securities	$ 34,448	$ —	$ (3)	$ —	$34,445
As reported:					
Cash and cash equivalents	$ 17,983	$ —	$ —	$ —	$17,983
Marketable securities	16,465	$ —	(3)	—	16,462
	$ 34,448	$ —	$ (3)	$ —	$34,445

	Fair Value Measurements at December 31, 2025				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Total
Cash and cash equivalents	$ 40,405	$ —	$ —	$ —	$40,405
U.S. Treasuries	40,058	23	—	—	40,081
Total cash, cash equivalents, and marketable securities	$ 80,463	$ 23	$ —	$ —	$80,486
As reported:					
Cash and cash equivalents	$ 40,405	$ —	$ —	$ —	$40,405
Marketable securities	40,058	23	—	—	40,081
	$ 80,463	$ 23	$ —	$ —	$80,486

None of the Company's available-for-sale marketable securities had remaining maturities longer than one year as of June 30, 2026 and December 31, 2025.

As of June 30, 2026, the aggregate unrealized losses on the Company's investment securities were immaterial. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable debt securities for the three and six months ended June 30, 2026.

4. Accrued Expenses and Other Current Liabilities

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

	June 30, 2026	December 31, 2025
Compensation and benefits	$ 2,536	$ 3,830
External research and development costs	7,722	6,361
Legal and professional fees	5,392	685
Other	2,203	1,415
Total accrued expenses and other current liabilities	$ 17,853	$ 12,291

5. Redeemable Convertible Preferred Stock

In February 2026, Takeda Ventures, Inc., elected to convert 7,085,290 shares of Series A-1 Preferred Stock into Common Stock ,par value $0.0001 per share ("Common Stock") at the conversion price of $1.1291.

At June 30, 2026 and December 31, 2025, the Preferred Stock is summarized below (in thousands, except share amounts):

	Amounts at June 30, 2026				
	Total Shares Authorized	Total Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Shares Issuable Upon Conversion
Series A-1 Preferred Stock	33,222,339	26,114,925	$ 29,486	$ 29,486	26,114,925
Series A-2 Preferred Stock	14,936,323	14,936,323	16,807	14,936	14,936,323
Series A-3 Preferred Stock	6,146,592	6,146,592	9,035	9,035	6,146,592
Series B Preferred Stock	76,187,917	76,187,917	114,732	115,044	76,187,917
Series C Preferred Stock	84,567,145	84,567,145	159,968	160,500	84,567,145
Total	215,060,316	207,952,902	$ 330,028	$ 329,001	207,952,902

	Amounts at December 31, 2025				
	Total Shares Authorized	Total Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Shares Issuable Upon Conversion
Series A-1 Preferred Stock	33,222,339	33,200,215	$ 37,486	$ 37,486	33,200,215
Series A-2 Preferred Stock	14,936,323	14,936,323	16,807	14,936	14,936,323
Series A-3 Preferred Stock	6,146,592	6,146,592	9,035	9,035	6,146,592
Series B Preferred Stock	76,187,917	76,187,917	114,732	115,044	76,187,917
Series C Preferred Stock	84,567,145	84,567,145	159,968	160,500	84,567,145
Total	215,060,316	215,038,192	$ 338,028	$ 337,001	215,038,192

There has been no change to the rights and preferences of the Preferred Stock. Refer to the notes to the consolidated financial statements, for the year ended December 31, 2025 for a detailed discussion of the rights and preferences of the Preferred Stock.

6. Common Stock

The Company's fourth amended and restated certificate of incorporation authorizes the Company to issue 274,320,131 shares of common stock. As of June 30, 2026, the Company had reserved 207,952,902 shares of common stock for the conversion of the Preferred Stock (Note 5), as applicable.

7. Stock-Based Compensation

2016 Equity Incentive Plan

In March 2016, the Company adopted the 2016 Stock Option and Grant Plan, or the 2016 Plan, which allows the granting of awards in the form of incentive stock options, nonqualified stock options, and stock grants, which may include restricted stock, to eligible employees, outside directors and consultants of the Company. The total number of common stock reserved for grant under the 2016 Plan was 48,749,161 shares as of June 30, 2026 and December 31, 2025, of which 5,330,455 and 4,475,263 shares remained available for future issuance as of June 30, 2026 and December 31, 2025, respectively. The 2016 Plan expired in March 2026 and no future awards may be granted thereunder. Effective immediately prior to the closing of the merger on August 3, 2026, the 2026 Equity Incentive Plan and the 2026 Employee Stock Purchase Plan became effective. Pursuant to the share reserve provisions of the 2026 Equity Incentive Plan, shares underlying outstanding awards granted under the

2016 Plan that are forfeited, canceled, expire unexercised or otherwise terminate without issuance of the underlying shares may become available for future issuance under the 2026 Equity Incentive Plan.

Stock Options

The Company estimates the fair value of the stock options issued using the Black-Scholes option pricing model on the date of grant. The key assumptions used to apply this pricing model were as follows:

	June 30,	
	2026	2025
Fair value of common stock	$ 0.78-0.96	$ 0.78 – 1.13
Risk-free interest rate	3.94%	4.26%
Expected dividend yield	—	—
Expected term (in years)	5.9	6.0
Expected volatility	82.71%	106.25%

The weighted average fair value of options granted during the six months ended June 30, 2026 and June 30, 2025 was $0.57 and $0.72, respectively.

The following table summarizes option activity under the 2016 Plan for the six months ended June 30, 2026:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	38,061,610	$ 0.77	6.9	$ 298
Options granted	5,353,691	0.79		
Options exercised	(1,161,144)	0.72		
Options forfeited	(2,441,148)	0.78		
Options expired	(4,177,316)	0.77		
Outstanding at June 30, 2026	35,635,693	$ 0.78	7.4	$ 6,528
Vested and exercisable at June 30, 2026	21,465,199	$ 0.77	6.7	$ 4,045
Unvested at June 30, 2026	14,170,494	$ 0.78	8.2	$ 2,102

During the six months ended June 30, 2026, 354,074 performance-based stock options granted in 2024 were forfeited, with approximately half forfeited due to employee termination and the remaining forfeited due to the related performance condition not being achieved. Additionally, during the six months ended June 30, 2026 the Company granted 1,883,750 performance-based awards that vest upon the achievement of specified performance goals, with a portion subject to continued service-based vesting thereafter. As of June 30, 2026, the applicable performance conditions for these awards were not deemed probable, and therefore no compensation expense has been recognized related to these awards.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company’s common stock for those options that had exercise prices lower than the fair value of the Company’s common stock.

The aggregate intrinsic value of options exercised totaled $0.3 million for the six months ended June 30, 2026 and less than $0.1 million for the six months ended June 30, 2025. As of June 30, 2026 there was $11.2 million of unrecognized compensation expense, which the Company expects to recognize over a weighted-average period of 2.1 years. Included in this amount is $1.0 million of unrecognized compensation expense relating to the performance-based awards described above.

The Company has recorded stock-based compensation expense as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 688	$ 1,168	$ 1,368	$ 1,993
General and administrative	864	1,593	1,638	2,878
	$1,552	$2,761	$3,006	$4,871

8. Income Taxes

No income tax expense was recorded during the three and six months ended June 30, 2026 or 2025. The Company maintained a full valuation allowance through June 30, 2026 due to uncertainty regarding its ability to utilize deferred tax assets.

9. Commitments and Contingencies

401(k) Plan

In January 2017, and as amended in February 2020, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Starting in 2020, the Company makes matching contributions at a rate of 100% of each employee's contribution up to a maximum employee contribution of 3% of eligible plan compensation. The Company made matching contributions of $0.1 million and $0.3 million for each of the three and six months ended June 30, 2026 and 2025, respectively.

Other Contractual Obligations

The Company enters into contracts in the normal course of business with third parties for preclinical research studies, upcoming clinical trials and testing and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by the Company upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of the service providers, up to the date of cancellation and in the case of certain arrangements may include noncancelable fees.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal Proceedings

The Company is not a party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of losses is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

Collaboration and License Agreement with University of Texas M.D. Anderson Cancer Center

In November 2020, The Company entered into a multi-year collaborative research and option agreement (the "Collaboration Agreement") with the Board of Regents (the "Board of Regents") of The University of Texas System, on behalf of the University of Texas M.D. Anderson Cancer Center ("M.D. Anderson"), designed to expedite the research and development of novel engineered TIL for the treatment of solid tumors. Pursuant to the Collaboration Agreement, as amended, the Company agreed to fund research activities of up to $8.3 million over approximately two years and received the option to obtain a license to certain intellectual property arising from the collaboration. The collaboration focused on developing TIL containing regulated membrane-bound IL15 ("mbIL15"), with the potential to enhance anti-tumor efficacy and reduce tumor burden in patients suffering from different types of solid tumors. The collaboration's purpose was to accelerate the development of cytoTIL™, including process and analytical development and clinical readiness activities. The Collaboration Agreement expired in 2023 and, prior to such expiration, the Company exercised its option to license certain intellectual property arising from the collaboration and subsequently entered into the resulting license agreement with the Board of Regents on behalf of M.D. Anderson (the ("M.D. Anderson License Agreement") in October 2021.

Under the M.D. Anderson License Agreement, the Company is obligated to pay to M.D. Anderson (a) a royalty on net sales of Developed Products and licensed products at a low single digit percentage (b) milestone payments of up to (i) $75.0 million upon the achievement of certain specified clinical and regulatory milestones and (ii) $90.0 million upon the achievement of certain specified sales milestones, which milestones may be payable with respect to multiple products and indications and (c) a share of certain consideration received by the Company from sublicensees under any sublicense agreements with third parties. As of June 30, 2026, no additional milestone payments were considered probable of achievement and, accordingly, no related liability has been recognized.

The M.D. Anderson License Agreement may be terminated by the Board of Regents upon notice for an uncured challenge of the Board of Regents' patents and by mutual agreement of us and the Board of Regents.

10. Leases

The Company has non-cancelable operating lease agreements for office space in Cambridge, Massachusetts and Bedford, Massachusetts, which run through January 2027 and December, 2028, respectively. Future minimum payments under these operating leases as of June 30, 2026 was $3.0 million. Operating lease cost was $0.7 million for each of the three months ended June 30, 2026 and 2025, and $1.4 million for each of the six months ended June 30, 2026 and 2025.

11. Net Loss Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (25,864)	$ (26,896)	$ (45,497)	$ (51,882)
Denominator				
Weighted-average common shares outstanding, basic and diluted	21,808,064	13,939,366	19,751,933	13,931,419
Net loss per share attributable to common stockholders, basic and diluted	$ (1.19)	$ (1.93)	$ (2.30)	$ (3.72)

Obsidian Sub excluded the following shares from the computation of diluted net loss per share attributable to common stockholders during the three and six months ended June 30, 2026 and 2025 because including them would have had an anti-dilutive effect:

	For the Three and Six Months Ended June 30,	
	2026	2025
Redeemable convertible preferred stock	207,952,902	215,038,192
Warrants to purchase Series A-1 redeemable convertible preferred stock	22,124	22,124
Options to purchase common stock	35,635,693	39,247,349
Total	243,610,719	254,307,665

12. Related Party Transactions

The Company entered into individual collaboration and license agreements with Celgene Corporation ("Celgene") in 2019 and 2020, respectively, and a collaboration agreement with Vertex Pharmaceuticals, Inc., ("Vertex") in 2021. Both Celgene and Vertex purchased the Company's Preferred Stock in connection with the collaboration agreements. All performance obligations under the collaboration agreements were satisfied in previous reporting periods. Accordingly, during the three and six months ended June 30, 2026, the Company did not recognize related party revenue associated with the collaboration agreements. The Celgene collaboration agreement was terminated in October 2025 and the Celgene license agreement was terminated in November 2025. The Vertex collaboration agreement expired in April 2025. No future revenue associated with these collaboration arrangements will be recognized.

13. Segment Information

The Company's Chief Executive Officer serves as the chief operating decision maker and reviews cash, cash equivalents and marketable securities as a measure of segment assets. As of June 30, 2026 and December 31, 2025, the Company's cash, cash equivalents and marketable securities were $34.4 million and $80.5 million, respectively.

The following tables illustrate information about segment revenue, significant segment expenses and segment operating loss for the three and six months ended June 30, 2026 and 2025:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenues:	$ —	$ —	$ —	$ —
Less(1):				
Research and development expenses(2):				
Compensation and related expenses	5,486	7,067	10,734	13,156
Drug discovery and platform	51	417	249	567
Clinical and manufacturing activities	12,637	12,428	20,448	24,447
Occupancy and all other costs	2,687	1,872	4,482	3,915
Total research and development expense	$ 20,861	$ 21,784	$ 35,913	$ 42,085
General and administrative expenses(3):				
Compensation and related expenses	2,096	2,228	4,359	4,576
Consulting and professional services	1,244	1,010	2,441	2,249
Occupancy and all other costs	387	475	701	1,081
Total general and administrative expense	$ 3,727	$ 3,713	$ 7,501	$ 7,906
Stock-based compensation	1,552	2,762	3,006	4,871
Other segment items(4)	(276)	(1,363)	(923)	(2,980)
Net loss	$ 25,864	$ 26,896	$ 45,497	$ 51,882

(1) The significant expense categories and amounts align with the segment-level information that is regularly provided to the chief operating decision maker.

(2) Research and development expense excludes stock-based compensation expense, which is presented separately below. Stock-based compensation expense excluded from research and development expense was $0.7 million and $1.2 million for the three months ended June 30, 2026 and 2025, respectively, and $1.4 million and $2.0 million for the six months ended June 30, 2026 and 2025, respectively.

(3) General and administrative expense excludes stock-based compensation expense, which is presented separately below. Stock-based compensation expense excluded from general and administrative expense was $0.8 million and $1.6 million for the three months ended June 30, 2026 and 2025, respectively, and $1.6 million and $2.9 million for the six months ended June 30, 2026 and 2025, respectively.

(4) Other segment items include interest and other income, net.

14. Subsequent Events

The Company has evaluated subsequent events through August 14, 2026, the date these condensed consolidated financial statements were issued, and determined that there have been no events that have occurred that would require adjustments to the Company's disclosures in the condensed consolidated financial statements, except for the following:

Galera Transaction

On August 3, 2026, Gazelle Parent, Inc. ("Parent") completed the previously announced mergers pursuant to the Agreement and Plan of the Merger (the "Merger Agreement") dated April 14, 2026, by and among Parent, the Company, Onyx MergerSub, Inc., Gazelle Merger Subsidiary, Inc. and Galera, such that Parent, who subsequently changed its name to Obsidian Therapeutics, Inc., became the parent of two wholly owned subsidiaries, Obsidian Therapeutics Sub, Inc. (formerly Obsidian Therapeutics, Inc. ("Legacy Obsidian")) and Galera Therapeutics, Inc. ("Legacy Galera").

In connection with the closing of the transaction, all outstanding shares of the Legacy Obsidian preferred stock and outstanding warrants were converted into shares of Legacy Obsidian common stock, which were subsequently converted into shares of Parent common stock calculated as defined in the Merger Agreement. Additionally, each outstanding and unexercised option to purchase Legacy Obsidian shares was converted into an option to purchase shares of Parent common stock, with necessary adjustments to the number of shares and exercise price pursuant to the terms of the Merger Agreement.

Concurrently with entering into the Merger Agreement, on April 14, 2026, Parent, Legacy Obsidian and Legacy Galera entered into a securities purchase agreement (the "Securities Purchase Agreement"), with certain qualified institutional buyers and/or accredited investors (the "Investors"). Pursuant to the Securities Purchase Agreement, and subject to the terms and conditions therein, the Investors agreed to purchase, and Legacy Galera agreed to issue and sell, immediately prior to the effective time of the Obsidian Merger (the "Obsidian Effective Time"), shares of Legacy Galera's Series C Non-Voting Convertible Preferred Stock, par value $0.001 per share ("Series C Preferred Stock"), for an aggregate purchase price of $350.0 million (the "Concurrent PIPE Financing"). The Concurrent PIPE Financing closed on July 31, 2026.

In connection with the Concurrent PIPE Financing, Parent and Legacy Galera and the investors in the Concurrent PIPE Financing entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which, among other things, the Company agreed to register for resale certain shares of common stock of Parent, par value $0.0001 per share ("Parent Common Stock") held by such Investors from time to time, including shares of Parent Common Stock issued in the Mergers in exchange for the shares of common stock, par value $0.001 per share, of Legacy Galera ("Legacy Galera Common Stock") issued in the Concurrent PIPE Financing.

On August 3, 2026, Parent and Legacy Obsidian entered into a Contingent Value Rights Agreement (the "CVR Agreement") with Equiniti Trust Company, LLC (the "Rights Agent"), pursuant to which stockholders of Legacy Galera of record as of July 31, 2026 received (1) one contingent value right, each a CVR, for each outstanding share of Legacy Galera Common Stock held by such stockholder on such date, representing the right to receive a pro rata portion of 80% of any potential future net proceeds received by Parent or its affiliates from the development, commercialization, licensing, sale or other disposition of the Legacy Product (as defined in the CVR Agreement), or related intellectual property during the five years following the closing and (2) the CVR for each outstanding share of Legacy Galera Common Stock held by such stockholder on such date, representing the right to receive a pro rata portion of 95% of any potential future net proceeds received by Parent or its affiliates from the Supportive-Care Product Divestiture (as defined in the CVR Agreement) during the ten years following the closing.

Parent began trading on the Nasdaq Capital Market under the ticker symbol "OBX" on August 4, 2026.

29,164,045 Shares of Common Stock

PRELIMINARY PROSPECTUS

, 2026

PART II

Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and The Nasdaq Capital Market, or Nasdaq, listing fee.

	Amount to be Paid
SEC registration fee	$ 74,490
Printing and mailing expenses	474,193
Legal fees and expenses	250,000
Accounting fees and expenses	60,000
Transfer agent and registrar fees and expenses	115,161
Miscellaneous expenses	76,156
Total	$ 1,050,000

Item 14. Indemnification of Directors and Officers.

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

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

- any breach of their duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for our directors, any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions as provided in Section 174 of the DGCL;
- any transaction from which the director or officer derived an improper personal benefit; or
- for our officers, any derivative action by or in the right of the corporation.

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

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

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

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended (the Securities Act).

Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Capital Stock

In February 2026, we issued 7,085,290 shares of common stock to an investor upon conversion of its Series A-1 convertible preferred stock. We did not receive any proceeds upon the conversion. The shares were issued without registration under the Securities Act, in reliance on the exemption provided by Section 3(a)(9) of the Securities Act.

In March 2024, we issued and sold an aggregate of 84,567,145 shares of Series C convertible preferred stock at a purchase price of $1.8979 per share for an aggregate purchase price of approximately $160.5 million.

In connection with the Mergers, Legacy Galera entered into a Securities Purchase Agreement in April 2026 with certain investors to consummate the PIPE Financing. Pursuant to the Securities Purchase Agreement, the investors agreed to purchase an aggregate of 29,166,166 shares of Legacy Galera Series C Non-Voting Convertible Preferred Stock, at a price of $12.00 per share, for aggregate gross proceeds of approximately $350.0 million.

No underwriters were involved in the foregoing sales of securities. Unless otherwise stated, the sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment

and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Grants and Exercises of Stock Options

Since January 1, 2023, we have granted stock options to purchase an aggregate of 43,329,428 shares of our common stock, with a weighted average exercise price of $0.78 per share, to employees, directors and consultants pursuant to the 2016 Plan. Since January 1, 2023, 4,381,127 shares of common stock have been issued upon the exercise of stock options pursuant to the 2016 Plan. Since January 1, 2023, 10,195,602 stock options previously issued pursuant to the 2016 Plan have been forfeited.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

Exhibit Number	Description
2.1*+	Agreement and Plan of Merger, dated as of April 14, 2026, by and among Galera Therapeutics, Inc., Obsidian Therapeutics, Inc., Gazelle Parent, Inc., Onyx MergerSub, Inc. and Gazelle Merger Subsidiary, Inc. (incorporated by reference from Exhibit 2.1 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
3.1*	Amended and Restated Certificate of Incorporation of Obsidian Therapeutics, Inc. (incorporated by reference from Exhibit 3.1 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
3.2*	Amended and Restated Bylaws of Obsidian Therapeutics, Inc. (incorporated by reference from Exhibit 3.2 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
4.1*	Galera Therapeutics, Inc. Warrant to Purchase Common Stock dated February 17, 2023 (incorporated by reference from Exhibit 4.1 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
5.1	Opinion of Goodwin Procter LLP.
10.1*+	Securities Purchase Agreement, dated as of April 14, 2026, by and among Gazelle Parent, Inc., Galera Therapeutics, Inc., Obsidian Therapeutics, Inc. and each of the Investors listed on Exhibit A thereto (incorporated by reference from Exhibit 10.1 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).

Exhibit Number	Description
10.2*+	Registration Rights Agreement, dated as of April 14, 2026, by and among Parent, Galera Therapeutics, Inc. and each of the Investors signatory thereto (incorporated by reference from Exhibit 10.2 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.3*+	Form of Lock-Up Agreement (incorporated by reference from Exhibit 10.3 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.4*+	Contingent Value Rights Agreement dated August 3, 2026, by and among Obsidian Therapeutics, Inc., Gazelle Parent, Inc. and Equiniti Trust Company, LLC (incorporated by reference from Exhibit 10.4 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.5*#	Form of Indemnification Agreement for Officers of Obsidian Therapeutics, Inc. (incorporated by reference from Exhibit 10.5 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.6*#	Form of Indemnification Agreement for Directors of Obsidian Therapeutics, Inc. (incorporated by reference from Exhibit 10.6 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.7*#	Obsidian Therapeutics, Inc. 2026 Equity Incentive Plan and form of award agreements thereunder (incorporated by reference from Exhibit 10.7 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.8*#	Obsidian Therapeutics, Inc. 2026 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.8 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.9*#	Non-Employee Director Compensation Policy (incorporated by reference from Exhibit 10.9 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.10*#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference from Exhibit 10.10 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.11*#	Executive Severance Plan (incorporated by reference from Exhibit 10.11 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.12*#	Form of Executive Employment Agreement (incorporated by reference from Exhibit 10.12 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.13*+	Nonexclusive License Agreement, by and between the Registrant and The University of Texas M.D. Anderson Cancer Center, dated October 19, 2021 (incorporated by reference from Exhibit 10.13 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
10.14*	Lease by and between the Registrant and Cambridge 1030 Mass Ave, LLC, dated May 19, 2017, as amended (incorporated by reference from Exhibit 10.14 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).

Exhibit Number	Description
10.15*	Lease by and between the Registrant and Patriots Park Owner, LLC, dated August 19, 2021 (incorporated by reference from Exhibit 10.15 to Obsidian Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-43430) filed with the Securities and Exchange Commission on August 3, 2026).
21.1	Subsidiaries of the Registrant.
23.1	Consent of KPMG LLP, independent registered public accounting firm.
23.2	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24.1	Power of Attorney
101.INS	Interactive Data File - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document.
101.SCH	XBRL Taxonomy Extension Schema
107	Filing Fee Table.

* Filed previously.
\# Indicates a management contract or any compensatory plan, contract or arrangement.
\+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(b)(2) or 601(a)(5) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

(b) Financial Statements Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

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

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

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the

foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated price range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Exhibit 107 "Filing Fee Table" in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Massachusetts, on the 28th day of August, 2026.

OBSIDIAN THERAPEUTICS, INC.

By: /s/ Madan Jagasia
Name: Madan Jagasia, M.D., M.S.
Title: Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints Madan Jagasia, M.D., M.S. and Julie Feder as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Madan Jagasia Madan Jagasia	Chief Executive Officer and Director (Principal Executive Officer)	August 28, 2026
/s/ Julie Feder Julie Feder	Chief Financial Officer (Principal Financial and Accounting Officer)	August 28, 2026
/s/ Maria Fardis Maria Fardis	Director, Chairperson	August 28, 2026
/s/ Peter Barrett Peter Barrett	Director	August 28, 2026
/s/ Heidi Hagen Heidi Hagen	Director	August 28, 2026
/s/ Matthew Norkunas Matthew Norkunas	Director	August 28, 2026
/s/ Rob Ross Rob Ross	Director	August 28, 2026

Exhibit 5.1

August 28, 2026

Obsidian Therapeutics, Inc.
1030 Massachusetts Avenue
Cambridge, MA 02138

Re: Securities Registered under Registration Statement on Form S-1

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-1 (as amended or supplemented, the "Registration Statement") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offering by Obsidian Therapeutics, Inc., a Delaware corporation (the "Company"), of up to 29,164,045 shares (the "Shares") of the Company's Common Stock, $0.0001 par value per share, to be sold by the selling stockholders listed in the Registration Statement under "Selling Stockholders."

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers of the Company.

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

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

This opinion letter and the opinion it contains shall be interpreted in accordance with the Core Opinion Principles as published in 74 *Business Lawyer* 815 (Summer 2019).

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

Very truly yours,

/s/ Goodwin Procter LLP
GOODWIN PROCTER LLP

Exhibit 21.1

Subsidiaries of Obsidian Therapeutics, Inc.

Legal Name of Subsidiary	Jurisdiction of Organization
Galera Therapeutics, Inc.	Delaware, United States
Obsidian Therapeutics Sub, Inc.	Delaware, United States
Obsidian Therapeutics Securities Corporation	Massachusetts, United States
Galera Labs, LLC	Missouri, United States
Nova Pharmaceuticals Operating, LLC	Delaware, United States

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the use of our report dated April 22, 2026, with respect to the consolidated financial statements of Obsidian Therapeutics, Inc. and subsidiary, included herein, and to the reference to our firm under the heading "Experts" in the prospectus.

/s/ KPMG LLP

Boston, Massachusetts
August 28, 2026

Calculation of Filing Fee Tables

S-1

Obsidian Therapeutics, Inc.

Table 1: Newly Registered and Carry Forward Securities ☐Not Applicable

		Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial Effective Date	Filing Fee Previously Paid in Connection with Unsold Securities to be Carried Forward
Newly Registered Securities													
Fees to be Paid	1	Equity	Common Stock, par value of $0.0001	Other	29,164,045	$ 17.7597	$ 517,944,689.99	0.0001381	$ 71,528.17				
Fees Previously Paid													
Carry Forward Securities													
Carry Forward Securities													
				Total Offering Amounts:			$ 517,944,689.99		$ 71,528.17				
				Total Fees Previously Paid:					$ 0.00				
				Total Fee Offsets:					$ 0.00				
				Net Fee Due:					$ 71,528.17				

Offering Note

1 (A) The amount of shares registered represents an aggregate of 29,164,045 shares of common stock, par value $0.0001 per share, of Obsidian Therapeutics, Inc. (the "Common Stock"), all of which were acquired by the selling stockholders named in the prospectus that forms a part of this registration statement (this "Registration Statement") in a private placement. Pursuant to Rule 416(a) promulgated under the Securities Act of 1933, as amended (the "Securities Act"), this Registration Statement shall also cover any additional shares of Common Stock that may be offered or become issuable as a result of stock splits, stock dividends, or other distribution, recapitalization or similar event or transaction effected without the receipt of consideration which results in an increase in the number of outstanding Common Stock. (B) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act and based upon the average of the high and low sales prices of the Common Stock, as reported on the Nasdaq Capital Market on August 27, 2026, which date is within five business days prior to the filing of this Registration Statement.

Table 2: Fee Offset Claims and Sources ☑Not Applicable

		Registrant or Filer Name	Form or Filing Type	File Number	Initial Filing Date	Filing Date	Fee Offset Claimed	Security Type Associated with Fee Offset Claimed	Security Title Associated with Fee Offset Claimed	Unsold Securities Associated with Fee Offset Claimed	Unsold Aggregate Offering Amount Associated with Fee Offset Claimed	Fee Paid with Fee Offset Source
Rules 457(b) and 0-11(a)(2)												
Fee Offset Claims												
Fee Offset Sources												
Rule 457(p)												
Fee Offset Claims												
Fee Offset Sources												

Table 3: Combined Prospectuses ☑Not Applicable

	Security Type	Security Class Title	Amount of Securities Previously Registered	Maximum Aggregate Offering Price of Securities Previously Registered	Form Type	File Number	Initial Effective Date