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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2022**

**OR**

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

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

**Commission file number: 001-36554**

# Ocular Therapeutix, Inc.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **20-5560161** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |
| **24 Crosby Drive**<br>**Bedford, MA** | **01730** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**(781) 357-4000**
**(Registrant's telephone number, including area code)**

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 13(a) of the Exchange Act. ☐

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

As of November 4, 2022, there were 77,010,385 shares of Common Stock, $0.0001 par value per share, outstanding.

**Ocular Therapeutix, Inc.**

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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "goals," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our ongoing and planned clinical trials, including our ongoing Phase 1 clinical trials of OTX-TKI for the treatment of wet age-related macular degeneration, or wet AMD, our planned Phase 1 clinical trial of OTX-TKI for the treatment of diabetic retinopathy, our planned Phase 2 clinical trial of OTX-TKI for the treatment of wet AMD, our ongoing Phase 2 clinical trial of OTX-TIC for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension, and our ongoing clinical trial to evaluate DEXTENZA® in pediatric subjects following cataract surgery in accordance with the U.S. Food and Drug Administration's post-approval requirement;

- our preclinical development programs, including our program to develop a gene therapy product candidate for the treatment of inherited and acquired ocular diseases and our program to develop a complement inhibitor product candidate for the treatment of dry age-related macular degeneration, or dry AMD;

- our commercialization efforts for our product DEXTENZA;

- our plans to develop, seek regulatory approval for and commercialize OTX-TKI, OTX-TIC, OTX-DED, OTX-CSI and other product candidates based on our proprietary bioresorbable hydrogel technology platform;

- our ability to manufacture DEXTENZA and our product candidates in compliance with Current Good Manufacturing Practices and in sufficient quantities for our clinical trials and commercial use;

- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for DEXTENZA and our product candidates;

- our estimates regarding future revenue; expenses; the sufficiency of our cash resources; our ability to fund our operating expenses, debt service obligations and capital expenditure requirements; and our needs for additional financing;

- our plans to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements and marketing and distribution arrangements;

- the potential advantages of DEXTENZA and our product candidates;

- the rate and degree of market acceptance and clinical utility of our products;

- our ability to secure and maintain reimbursement for our products as well as the associated procedures to insert, implant or inject our products;

- our estimates regarding the market opportunity for DEXTENZA and our product candidates;

- our license agreement and collaboration with AffaMed Therapeutics Limited under which we are collaborating on the development and commercialization of DEXTENZA and our product candidate OTX-TIC in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations;

- our capabilities and strategy, and the costs and timing of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to DEXTENZA, ReSure Sealant and any additional products for which we may obtain marketing approval in the future;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of government laws and regulations;
- the costs and outcomes of legal actions and proceedings;
- uncertainty regarding the extent to which the COVID-19 pandemic and related response measures will adversely affect our business, results of operations and financial condition; and
- our competitive position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in Part II, Item 1A — Risk Factors section, and in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission, or the SEC, on February 28, 2022, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, licensing agreements, collaborations, or investments we may make.

You should read this Quarterly Report on Form 10-Q, the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q, and our other periodic reports completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements included in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q. We do not assume, and we expressly disclaim, any obligation or undertaking to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. All of the market data used in this Quarterly Report on Form 10-Q involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. While we believe that the information from these industry publications, surveys and studies is reliable, we have not independently verified such data. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors.”

This Quarterly Report on Form 10-Q contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report and the documents incorporated by reference herein may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

**Ocular Therapeutix, Inc.**

**Condensed Consolidated Balance Sheets**
**(In thousands, except share and per share data)**
**(Unaudited)**

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 120,950 | $ 164,164 |
| Accounts receivable, net | 19,802 | 21,135 |
| Inventory | 1,545 | 1,250 |
| Prepaid expenses and other current assets | 3,318 | 4,751 |
| Total current assets | 145,615 | 191,300 |
| Property and equipment, net | 7,196 | 6,956 |
| Restricted cash | 1,764 | 1,764 |
| Operating lease assets | 4,004 | 4,867 |
| Total assets | $ 158,579 | $ 204,887 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,308 | $ 4,592 |
| Accrued expenses and other current liabilities | 21,614 | 20,121 |
| Deferred revenue | 603 | — |
| Operating lease liabilities | 1,744 | 1,624 |
| Total current liabilities | 29,269 | 26,337 |
| Other liabilities: | | |
| Operating lease liabilities, net of current portion | 4,610 | 5,924 |
| Derivative liability | 11,594 | 20,192 |
| Deferred revenue, net of current portion | 13,533 | 13,000 |
| Notes payable, net of discount | 25,192 | 25,000 |
| 2026 convertible notes, net | 28,152 | 26,435 |
| Total liabilities | 112,350 | 116,888 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2022 and December 31, 2021, respectively | — | — |
| Common stock, $0.0001 par value; 200,000,000 shares authorized and 77,010,385 and 76,731,940 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively | 8 | 8 |
| Additional paid-in capital | 647,521 | 633,795 |
| Accumulated deficit | (601,300) | (545,804) |
| Total stockholders' equity | 46,229 | 87,999 |
| Total liabilities and stockholders' equity | $ 158,579 | $ 204,887 |

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

**Ocular Therapeutix, Inc.**

**Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)**
**(In thousands, except share and per share data)**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Revenue: | | | | |
| Product revenue, net | $ 11,913 | $ 12,153 | $ 36,555 | $ 31,214 |
| Collaboration revenue | 52 | — | 864 | — |
| Total revenue, net | 11,965 | 12,153 | 37,419 | 31,214 |
| Costs and operating expenses: | | | | |
| Cost of product revenue | 1,073 | 1,310 | 3,528 | 3,298 |
| Research and development | 13,719 | 12,719 | 39,919 | 37,505 |
| Selling and marketing | 10,186 | 9,576 | 29,390 | 26,054 |
| General and administrative | 8,531 | 8,077 | 23,875 | 24,345 |
| Total costs and operating expenses | 33,509 | 31,682 | 96,712 | 91,202 |
| Loss from operations | (21,544) | (19,529) | (59,293) | (59,988) |
| Other income (expense): | | | | |
| Interest income | 285 | 7 | 375 | 27 |
| Interest expense | (1,797) | (1,658) | (5,175) | (4,991) |
| Change in fair value of derivative liability | (1,133) | 23,837 | 8,598 | 62,249 |
| Other income (expense), net | 1 | — | (1) | — |
| Total other (expense) income, net | (2,644) | 22,186 | 3,797 | 57,285 |
| Net (loss) income | $ (24,188) | $ 2,657 | $ (55,496) | $ (2,703) |
| Net (loss) income per share, basic | $ (0.31) | $ 0.03 | $ (0.72) | $ (0.04) |
| Weighted average common shares outstanding, basic | 76,975,839 | 76,552,060 | 76,829,434 | 76,317,563 |
| Net (loss) per share, diluted | $ (0.31) | $ (0.23) | $ (0.73) | $ (0.75) |
| Weighted average common shares outstanding, diluted | 76,975,839 | 85,446,886 | 82,598,666 | 82,086,795 |

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

**Ocular Therapeutix, Inc.**

**Condensed Consolidated Statements of Cash Flows**
**(In thousands)**
**(Unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| **Cash flows from operating activities:** | | |
| Net loss | $ (55,496) | $ (2,703) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Stock-based compensation expense | 12,730 | 11,136 |
| Non-cash interest expense | 3,616 | 3,440 |
| Change in fair value of derivative liability | (8,598) | (62,249) |
| Depreciation and amortization expense | 1,618 | 1,851 |
| Loss on disposal of property and equipment | 1 | (1) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 1,333 | (7,300) |
| Prepaid expenses and other current assets | 1,433 | 773 |
| Inventory | (295) | (21) |
| Operating lease assets | 863 | 715 |
| Accounts payable | 501 | 1,430 |
| Accrued expenses | (293) | 3,529 |
| Deferred revenue | 1,136 | — |
| Operating lease liabilities | (1,194) | (997) |
| Net cash used in operating activities | (42,645) | (50,397) |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (1,565) | (563) |
| Net cash used in investing activities | (1,565) | (563) |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of notes payable, net | — | 3,722 |
| Proceeds from exercise of stock options | 514 | 2,414 |
| Proceeds from issuance of common stock pursuant to employee stock purchase plan | 482 | 490 |
| Issuance costs from the issuance of common stock upon public offering | — | (275) |
| Repayment of notes payable | — | (4,167) |
| Net cash provided by financing activities | 996 | 2,184 |
| **Net decrease in cash, cash equivalents and restricted cash** | (43,214) | (48,776) |
| Cash, cash equivalents and restricted cash at beginning of period | 165,928 | 229,821 |
| Cash, cash equivalents and restricted cash at end of period | $ 122,714 | $ 181,045 |
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for interest | $ 1,521 | $ 1,443 |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Additions to property and equipment included in accounts payable and accrued expenses | $ 477 | $ 199 |

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

**Ocular Therapeutix, Inc.**

**Condensed Consolidated Statements of Stockholders' Equity**
**(In thousands, except share data)**
**(Unaudited)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| | Shares | Par Value | | | |
| **Balances at December 31, 2021** | 76,731,940 | $ 8 | $ 633,795 | $ (545,804) | $ 87,999 |
| Issuance of common stock upon exercise of stock options | 27,674 | — | 129 | — | 129 |
| Stock-based compensation expense | — | — | 4,209 | — | 4,209 |
| Net loss | — | — | — | (12,542) | (12,542) |
| **Balances at March 31, 2022** | 76,759,614 | $ 8 | $ 638,133 | $ (558,346) | $ 79,795 |
| Issuance of common stock upon exercise of stock options | 9,469 | — | 11 | — | 11 |
| Issuance of common stock in connection with employee stock purchase plan | 140,943 | — | 482 | — | 482 |
| Stock-based compensation expense | — | — | 4,281 | — | 4,281 |
| Net loss | — | — | — | (18,766) | (18,766) |
| **Balances at June 30, 2022** | 76,910,026 | $ 8 | $ 642,907 | $ (577,112) | $ 65,803 |
| Issuance of common stock upon exercise of stock options | 100,359 | — | 374 | — | 374 |
| Stock-based compensation expense | — | — | 4,240 | — | 4,240 |
| Net loss | — | — | — | (24,188) | (24,188) |
| **Balances at September 30, 2022** | 77,010,385 | $ 8 | $ 647,521 | $ (601,300) | $ 46,229 |

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

**Ocular Therapeutix, Inc.**

**Condensed Consolidated Statements of Stockholders' Equity**
**(In thousands, except share data)**
**(Unaudited)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| | Shares | Par Value | | | |
| **Balances at December 31, 2020** | 75,996,732 | $ 8 | $ 615,338 | $ (539,251) | $ 76,095 |
| Issuance of common stock upon exercise of stock options | 228,241 | — | 1,197 | — | 1,197 |
| Issuance of common stock upon cashless exercise of warrant | 11,737 | — | — | — | — |
| Issuance costs associated with common stock public offering | — | — | (91) | — | (91) |
| Stock-based compensation expense | — | — | 3,086 | — | 3,086 |
| Net income | — | — | — | 3,121 | 3,121 |
| **Balances at March 31, 2021** | 76,236,710 | $ 8 | $ 619,530 | $ (536,130) | $ 83,408 |
| Issuance of common stock upon exercise of stock options | 177,256 | — | 538 | — | 538 |
| Issuance of common stock in connection with employee stock purchase plan | 40,631 | — | 490 | — | 490 |
| Stock-based compensation expense | — | — | 4,292 | — | 4,292 |
| Net loss | — | — | — | (8,481) | (8,481) |
| **Balances at June 30, 2021** | 76,454,597 | $ 8 | $ 624,850 | $ (544,611) | $ 80,247 |
| Issuance of common stock upon exercise of stock options | 152,371 | — | 678 | — | 678 |
| Stock-based compensation expense | — | — | 3,758 | — | 3,758 |
| Net income | — | — | — | 2,657 | 2,657 |
| **Balances at September 30, 2021** | 76,606,968 | $ 8 | $ 629,286 | $ (541,954) | $ 87,340 |

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

**Ocular Therapeutix, Inc.**

**Notes to the Condensed Consolidated Financial Statements**
**(Amounts in thousands, except share and per share data)**
**(Unaudited)**

## 1. Nature of the Business and Basis of Presentation

Ocular Therapeutix, Inc. (the "Company") was incorporated on September 12, 2006 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on the formulation, development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary, bioresorbable hydrogel platform technology. The Company's product candidates are designed to provide differentiated drug delivery solutions that reduce the complexity and burden of the current standard of care by creating local programmed-release alternatives. Since inception, the Company's operations have been primarily focused on organizing and staffing the Company, acquiring rights to intellectual property, business planning, raising capital, developing its technology, identifying product candidates, undertaking preclinical studies and clinical trials, manufacturing its products and product candidates, building its sales and marketing infrastructure for the commercialization of the Company's approved products and product candidates, and commercializing its approved products.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, regulatory approval and compliance, reimbursement, uncertainty of market acceptance of products and the need to obtain additional financing. Newly-approved products will require significant sales, marketing and distribution support up to and including upon their launch. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization.

As of September 30, 2022, the Company had two U.S. Food and Drug Administration ("FDA")-approved products in commercialization in the United States: DEXTENZA® (dexamethasone insert) 0.4mg, an intracanalicular insert for the treatment of post-surgical ocular inflammation and pain and ocular itching associated with allergic conjunctivitis, and ReSure® Sealant, an ophthalmic device designed to prevent wound leaks in corneal incisions following cataract surgery. While ReSure Sealant is commercially available in the United States, it does not receive sales support, is not currently being manufactured by the Company, and has not in the past generated, nor is it anticipated to in the future to generate, material revenues. The Company's most advanced product candidates are in either Phase 1 or Phase 2 of clinical stage development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval and adequate reimbursement or that any approved products will be commercially viable. 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. The Company operates in an environment of rapidly changing technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants. The Company may not be able to generate significant revenue from sales of any product for several years, if at all. Accordingly, the Company will need to obtain additional capital to finance its operations.

The Company has incurred losses and negative cash flows from operations since its inception, and the Company expects to continue to generate operating losses and negative cash flows from operations in the foreseeable future. As of September 30, 2022, the Company had an accumulated deficit of $601,300. Based on its current plans and forecasted expenses, which include estimates related to anticipated cash inflows from DEXTENZA product sales and cash outflows from operating expenses, the Company believes that its existing cash and cash equivalents of $120,950, as of September 30, 2022, will enable it to fund its planned operating expenses, debt service obligations and capital expenditure requirements through at least the next 12 months from the date these condensed consolidated financial statements were issued. The future viability of the Company beyond that point is dependent on its ability to generate cash flows from the sale of DEXTENZA and raise additional capital to finance its operations. The Company will need to finance its operations through public or private securities offerings, debt financings, royalty financings or other sources, which may include licensing, collaborations or other strategic transactions or arrangements. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. If the Company is unable to obtain funding, the Company could

be forced to delay, reduce or eliminate some or all of its research and development programs for product candidates, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The significant accounting policies used in preparation of these financial statements are consistent with those described in Note 2 - Summary of Significant Accounting Policies in our 2021 Annual Report on Form 10-K.

***Unaudited Interim Financial Information***

The balance sheet at December 31, 2021 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2022 and results of operations and cash flows for the three and nine months ended September 30, 2022 and 2021 have been made. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

***Effects of COVID-19***

The pandemic caused by an outbreak of a new strain of coronavirus, ( the "COVID-19 pandemic") that is affecting the U.S. and global economy and financial markets and the related responses of government, businesses and individuals are impacting our employees, patients, customers, communities and business operations. The implementation of travel bans and restrictions, quarantines, shelter-in-place/stay-at-home and social distancing orders and shutdowns, for example, affected our business in 2020 and 2021. During the first nine months of 2022, the COVID-19 pandemic and related employee recruitment and retention challenges for ambulatory surgical centers ("ASCs"), and hospital out-patient departments ("HOPDs") slowed the overall pace of cataract procedures performed in the United States, thereby reducing the number of opportunities for ophthalmologists to use DEXTENZA as a treatment for post-surgical ocular inflammation and pain. In addition, recruitment and retention challenges with regards to the Company's own sales force have adversely affected its ability to market DEXTENZA to ophthalmologists and in the office setting. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact the Company's business, results of operations and financial condition and those of the Company's customers, vendors, suppliers, and collaboration partners will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Management continues to actively monitor this situation and the possible effects on the Company's financial condition, liquidity, operations, suppliers, industry, and workforce. For additional information on risks posed by the COVID-19 pandemic, please see "Item 1A — Risk Factors — Risks Related to the Coronavirus Pandemic," included our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 28, 2022.

**2. Summary of Significant Accounting Policies**

***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 and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not

limited to, revenue recognition, clinical trial accruals and the fair value of derivatives. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results may differ from these estimates.

***Concentration of Credit Risk and of Significant Suppliers and Customers***

The Company is dependent on a small number of third-party manufacturers to supply products for research and development activities in its preclinical and clinical programs and for sales of its products. The Company's development programs as well as revenue from future product sales could be adversely affected by a significant interruption in the supply of any of the components of these products.

For the three and nine months ended September 30, 2022, three specialty distributor customers accounted for 42%, 30%, and 14%, and 41%, 27% and 18%, respectively, of the Company's total gross product revenue, and no other customer accounted for more than 10% of the Company's total gross product revenue.

At September 30, 2022, three specialty distributor customers accounted for 44%, 30% and 15% of the Company's total accounts receivable, and no other customer accounted for more than 10% of the Company's total accounts receivable at September 30, 2022.

For the three and nine months ended September 30, 2021, three specialty distributor customers accounted for 44%, 28%, and 16%, and 44%, 26% and 15%, respectively, of the Company's total gross product revenue, and no other customer accounted for more than 10% of the Company's total gross product revenue.

At December 31, 2021, three specialty distributor customers accounted for 42%, 26% and 21% of the Company's total accounts receivable. No other customer accounted for more than 10% of total accounts receivable at December 31, 2021.

***Recently Adopted Accounting Pronouncements***

Effective January 1, 2022, the Company adopted ASU No. 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40), which amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related earnings per share guidance for both Subtopics. The adoption of this standard did not have any impact on the Company's condensed consolidated financial statements.

### 3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2022 and December 31, 2021 and indicate the level of the fair value hierarchy utilized to determine such fair value:

| | Fair Value Measurements as of September 30, 2022 Using: | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 48,556 | $ — | $ — | $ 48,556 |
| **Liability:** | | | | |
| Derivative liability (Note 7) | $ — | $ — | $ 11,594 | $ 11,594 |

| | Fair Value Measurements as of December 31, 2021 Using: | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 62,392 | $ — | $ — | $ 62,392 |
| **Liability:** | | | | |
| Derivative liability (Note 7) | $ — | $ — | $ 20,192 | $ 20,192 |

### 4. Restricted Cash

The Company held restricted cash of $1,764 at September 30, 2022 and December 31, 2021, on its condensed consolidated balance sheet. The Company held restricted cash as security deposits for the lease of its research and development space, manufacturing space and corporate headquarters.

The Company's condensed consolidated statements of cash flows include restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on such statements. A reconciliation of the cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same amounts shown in the condensed consolidated statement of cash flows is as follows:

| | September 30, 2022 | September 30, 2021 |
|---|---|---|
| Cash and cash equivalents | $ 120,950 | $ 179,281 |
| Restricted cash | 1,764 | 1,764 |
| Total cash, cash equivalents and restricted cash | $ 122,714 | $ 181,045 |

### 5. Inventory

The Company values its inventories at the lower of cost or estimated net realizable value.

Inventory consisted of the following:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Raw materials | $ 317 | $ 388 |
| Work-in-process | 885 | 605 |
| Finished goods | 343 | 257 |
| | $ 1,545 | $ 1,250 |

**6. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities as of September 30, 2022 and December 31, 2021 consisted of the following:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Accrued payroll and related expenses | $ 6,700 | $ 6,597 |
| Accrued rebates and programs | 2,666 | 3,615 |
| Accrued professional fees | 1,306 | 1,227 |
| Accrued research and development expenses | 1,565 | 1,102 |
| Accrued interest payable on 2026 convertible notes | 8,181 | 6,475 |
| Accrued other | 1,196 | 1,105 |
| | $ 21,614 | $ 20,121 |

**7. Derivative Liability**

The unsecured senior subordinated convertible notes (the “2026 Convertible Notes”) (Note 8) contains an embedded conversion option that meets the criteria to be bifurcated and accounted for separately (the “Derivative Liability”) from the 2026 Convertible Notes. The Derivative Liability was recorded at fair value upon the issuance of the 2026 Convertible Notes and is subsequently remeasured to fair value at each reporting period. The Derivative Liability is valued using a “with-and-without” method. The “with-and-without” methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the embedded conversion option. The difference between the entire instrument with the embedded conversion option compared to the instrument without the embedded conversion option is the fair value of the derivative, recorded as the Derivative Liability in the Company’s condensed consolidated balance sheet.

The estimated fair value of the 2026 Convertible Notes was $42,721 at September 30, 2022. The fair value of the 2026 Convertible Notes on an as-is basis is estimated utilizing a binomial lattice model which requires the use of Level 3 unobservable inputs. The main inputs when determining the fair value are the common stock price and bond yield which are updated each period to reflect the yield of a comparable instrument issued as of the valuation date. The estimated fair value presented is not necessarily indicative of an amount that could be realized in a current market exchange. The use of alternative inputs and estimation methodologies could have a material effect on these estimates of fair value. The main inputs to valuing the 2026 Convertible Notes with the conversion option are as follows:

| | As of | |
|---|---|---|
| | September 30, 2022 | December 31, 2021 |
| Company's stock price | $ 4.15 | $ 6.97 |
| Volatility | 100.3 % | 82.6 % |
| Bond yield | 17.1 % | 12.6 % |

A roll-forward of the derivative liability is as follows:

| | As of September 30, 2022 |
|---|---|
| Balance at December 31, 2021 | $ 20,192 |
| Change in fair value | (8,598) |
| Balance at September 30, 2022 | $ 11,594 |

**8. Convertible Notes**

On March 1, 2019, the Company issued $37,500 of 2026 Convertible Notes. Each 2026 Convertible Note accrues interest at an annual rate of 6% of its outstanding principal amount, which is payable, along with the principal amount at maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed. The Company presents accrued interest in accrued current liabilities because the 2026 Convertible Notes are currently convertible and the interest is payable in cash. The effective annual interest rate for the 2026 Convertible Notes was 14.8% through September 30, 2022.

The holders of the 2026 Convertible Notes may convert all or part of the outstanding principal amount of their 2026 Convertible Notes into shares of the Company’s common stock, par value $0.0001 per share, prior to maturity and provided that no conversion results in a holder beneficially owning more than 19.99% of the issued and outstanding common stock of the Company. The conversion rate is 153.8462 shares of the Company’s common stock per $1,000 principal amount of the 2026 Convertible Notes, which is equivalent to an initial conversion price of $6.50 per share. The conversion rate is subject to adjustment in customary circumstances such as stock splits or similar changes to the Company’s capitalization.

At its election, the Company may choose to make such conversion payment in cash, in shares of common stock, or a combination thereof. Upon any conversion of any 2026 Convertible Note, the Company is obligated to make a cash payment to the holder of such 2026 Convertible Note for any interest accrued but unpaid on the principal amount converted. Upon the occurrence of a Corporate Transaction (as defined below), each holder has the option to require the Company to repurchase all or part of the outstanding principal amount of such note at a repurchase price equal to 100% of the outstanding principal amount of the 2026 Convertible Note to be repurchased, plus accrued and unpaid interest to but excluding the repurchase date. In addition, each holder is entitled to receive an additional make-whole cash payment in accordance with a table set forth in each 2026 Convertible Note.

Upon conversion by the holder, the Company has the right to select the settlement of the conversion in shares of common stock, cash, or in a combination thereof. In addition, the Company is obligated to make a cash payment to the holder of such 2026 Convertible Note for any interest accrued but unpaid on the principal amount converted.

- If the Company elects to satisfy such conversion by shares of common stock, the Company shall deliver to the converting holder in respect of each $1,000 principal amount of 2026 Convertible Notes being converted a number of common shares equal to the conversion rate in effect on the conversion date;

- If the Company elects to satisfy such conversion by cash settlement, the Company shall pay to the converting holder in respect of each $1,000 principal amount of 2026 Convertible Notes being converted cash in an amount equal to the sum of the Daily Conversion Values (as defined below) for each of the twenty (20) consecutive trading days during a specified period. The "Daily Conversion Values" is defined as each of the 20 consecutive trading days during the specified period, 5.0% of the product of (a) the conversion rate on such trading day and (b) the Daily VWAP on such trading day. The Daily VWAP is defined as each of the 20 consecutive trading days during the applicable observation period, the per share volume-weighted average price as displayed under the heading "Bloomberg VWAP" on the Bloomberg page for the Company.

- If the Company elects to satisfy such conversion by combination, the Company shall pay or deliver, as the case may be, in respect of each $1,000 principal amount of 2026 Convertible Notes being converted, a settlement amount equal to the sum of the Daily Settlement Amounts (as defined below) for each of the twenty (20) consecutive trading days during the specified period. The "Daily Settlement Amount" is defined as, for each of the 20 consecutive trading days during the specified period: (a) cash in an amount equal to the lesser of (i) the Daily Measurement Value (as defined below) and (ii) the Daily Conversion Value on such Trading Day; and (b) if the Daily Conversion Value on such trading day exceeds the Daily Measurement Value, a number of shares equal to (i) the difference between the Daily Conversion Value and the Daily Measurement Value, divided by (ii) the Daily VWAP for such Trading Day. The "Daily Measurement Value" is defined as the Specified Dollar Amount (as defined below), if any, divided by 20. The "Specified Dollar Amount" is defined as the maximum cash amount per $1,000 principal amount of Notes to be received upon conversion as specified in the notice specifying the Company's chosen settlement method.

In the event of a Corporate Transaction, the noteholder shall have the right to either (a) convert all of the unpaid principal at the conversion rate and receive a cash payment equal to (i) the outstanding accrued but unpaid interest under the 2026 Convertible Note to, but excluding, the corporate transaction conversion date (to the extent such date occurs prior to March 1, 2026, the maturity date of the 2026 Convertible Notes) plus (ii) an additional amount of consideration based on a sliding scale depending on the date of such as Corporate transaction or (b) require the Company to repurchase all or part of the outstanding principal amount of such 2026 Convertible Note at a repurchase price equal to 100% of the outstanding principal amount of the 2026 Convertible Note to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date.

A corporate transaction includes (i) a merger or consolidation executed through a tender offer or change of control (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation); (ii) a sale, lease, transfer, of all or substantially all of the assets of the Company; or (iii) if the Company's common stock ceases to be listed or quoted on any of the New York Stock Exchange, the Nasdaq Global Select Market, the Nasdaq Global Market or the Nasdaq Capital Market (the "Corporate Transaction").

On or after March 1, 2022, if the last reported sale price of the common stock has been at least 130% of the conversion rate then in effect for 20 of the preceding 30 trading days (including the last trading day of such period), the Company is entitled, at its option, to redeem all or part of the outstanding principal amount of the 2026 Convertible Notes, on a pro rata basis, at an optional redemption price equal to 100% of the outstanding principal amount of the 2026 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the optional redemption date.

The 2026 Convertible Notes are subject to acceleration upon the occurrence of specified events of default, including a default or breach of certain contracts material to the Company and the delisting and deregistration of the Company's common stock.

As discussed in Note 7, the Company determined that the embedded conversion option is required to be separated from the 2026 Convertible Notes and accounted for as a freestanding derivative instrument subject to derivative accounting. The allocation of proceeds to the conversion option results in a discount on the 2026 Convertible Notes. The Company is amortizing the discount to interest expense over the term of the 2026 Convertible Notes using the effective interest method.

The terms and conditions of the 2026 Convertible Notes are described in the Company's periodic reports including its Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 28, 2022.

A summary of the 2026 Convertible Notes at September 30, 2022 and December 31, 2021 is as follows:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| 2026 Convertible Notes | $ 37,500 | $ 37,500 |
| Less: unamortized discount | (9,348) | (11,065) |
| Total | $ 28,152 | $ 26,435 |

Accrued interest related to the 2026 Convertible Notes amounted to $8,181 and $6,475 at September 30, 2022 and December 31, 2021, respectively.

**9. Income Taxes**

The Company did not provide for any income taxes in its condensed consolidated statement of operations and comprehensive income (loss) for the three and nine month periods ended September 30, 2022 or 2021. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at September 30, 2022 and December 31, 2021, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

**10. Collaboration Agreements**

***AffaMed License Agreement***

In October 2020, the Company entered into a license agreement with AffaMed Therapeutics Limited ("AffaMed") for the development and commercialization of the Company's DEXTENZA product regarding ocular inflammation and pain following cataract surgery and ocular itching associated with allergic conjunctivitis and for development of the Company's OTX-TIC product candidate (collectively with DEXTENZA, the "AffaMed Licensed Products") regarding open-angle glaucoma or ocular hypertension, in each case in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations. The Company and AffaMed subsequently amended the license agreement in October 2021 (as amended, the "License Agreement"). The Company retains development and commercialization rights for the AffaMed Licensed Products in the rest of the world.

The terms and conditions of the License Agreement are described in the Company's periodic reports including its Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022.

During the three months ended March 31, 2022, the Company invoiced AffaMed $2,000 for a clinical trial support payment, under the License Agreement, in connection with the initiation of the OTX-TIC Phase 2 clinical trial. The Company concluded this clinical support payment was no longer constrained and has allocated the amount to the performance obligation under the License Agreement to conduct a Phase 2 clinical trial of OTX-TIC.

For the Phase 2 clinical trial of OTX-TIC, collaboration revenue related to this performance obligation is recognized under an input method using the ratio of effort incurred to date compared to the total estimated effort required to complete the performance obligation. The calculation of the total estimated effort includes the total amount of forecasted costs associated with the completion of the Phase 2 clinical trial, as well as the assumed timing of this activity. Such cost estimates include forecasted direct labor and material costs, subcontractor costs, and external contract research organization, or CRO, costs.

The Company recognized $52 and $864 of collaboration revenue related to this performance obligation under the License Agreement for the three and nine months ended September 30, 2022.

As of September 30, 2022, the aggregate amount of the transaction price allocated to performance obligations that are partially unsatisfied was $1,136. This amount is expected to be recognized upon the satisfaction of the performance obligations through June 2025.

Deferred revenue activity for the nine months ended September 30, 2022 was as follows:

| | Deferred Revenue |
|---|---|
| Deferred revenue at December 31, 2021 | $ 13,000 |
| Additions | 2,000 |
| Amounts recognized into revenue | (864) |
| Deferred revenue at September 30, 2022 | $ 14,136 |

As of September 30, 2022, the aggregate amount of the transaction price allocated to DEXTENZA product and OTX-TIC product performance obligations that are partially unsatisfied was $13,000. This amount is expected to be recognized as performance obligations are satisfied. The Company recognizes revenue related to the amounts allocated to the combined performance obligations for the development and commercialization of the Company's DEXTENZA product regarding ocular inflammation and pain following cataract surgery and allergic conjunctivitis and the Company's OTX-TIC product candidate based on the point in time upon which control of supply is transferred to AffaMed for each delivery of the associated supply. The Company currently expects to recognize the revenue over a period of approximately seven to eight years commencing on the date the Company begins delivering product to AffaMed. This estimate of this period considers the timing of development and commercial activities under the License Agreement and may be reduced or increased based on the various activities as directed by the joint committees, decisions made by AffaMed, regulatory feedback or other factors not currently known.

**11. Notes Payable**

The Company entered into a credit and security agreement in 2014 (as amended to date, the "Credit Agreement") establishing the Company's credit facility (the "Credit Facility"). Under the Credit Facility, the Company has a total borrowing capacity of $25,000, which was fully drawn down as of September 30, 2022. The carrying value of the Company's variable interest rate notes payable are recorded at amortized cost, which approximates fair value due to their short-term nature.

The terms and conditions of the Credit Agreement and the Credit Facility are described in the Company's periodic reports including its Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022.

Borrowings outstanding are as follows:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Borrowings outstanding | $ 25,000 | $ 25,000 |
| Accrued exit fee | 278 | 110 |
| Unamortized discount | (86) | (110) |
| Long-term notes payable | $ 25,192 | $ 25,000 |

As of September 30, 2022, the annual requirement for the repayment of principal for the Credit Facility, inclusive of the final payment of $875 due at expiration, was as follows:

| Year Ending December 31, | Principal | Final Payment | Total |
|---|---|---|---|
| 2022 (October 1 to December 31) | — | — | — |
| 2023 | — | — | — |
| 2024 | 8,333 | — | 8,333 |
| 2025 | 16,667 | 875 | 17,542 |
| | $ 25,000 | $ 875 | $ 25,875 |

**12. Net (Loss) Income Per Share**

Basic net (loss) income per share was calculated as follows for the three and nine months ended September 30, 2022 and 2021.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Numerator: | | | | |
| Net (loss) income attributable to common stockholders | $ (24,188) | $ 2,657 | $ (55,496) | $ (2,703) |
| Denominator: | | | | |
| Weighted average common shares outstanding, basic | 76,975,839 | 76,552,060 | 76,829,434 | 76,317,563 |
| Net (loss) income per share - basic | $ (0.31) | $ 0.03 | $ (0.72) | $ (0.04) |

For the three months ended September 30, 2022 there is no dilutive impact. Therefore, diluted net loss per share is the same as basic net loss per share. Diluted net (loss) income per share was calculated as follows for the nine months ended September 30, 2022 and the three and nine months ended September 30, 2021:

| | Three Months Ended September 30, | Nine Months Ended September 30, | |
|---|---|---|---|
| | 2021 | 2022 | 2021 |
| Net income (loss) attributable to common stockholders, basic | $ 2,657 | $ (55,496) | $ (2,703) |
| Interest expense on 2026 Convertible Notes | 1,113 | 3,425 | 3,286 |
| Change in fair value of derivative liability | (23,837) | (8,598) | (62,249) |
| Net loss attributable to common stockholders, diluted | $ (20,067) | $ (60,669) | $ (61,666) |
| | | | |
| Weighted average common shares outstanding, basic | 76,552,060 | 76,829,434 | 76,317,563 |
| Dilutive options (treasury stock method) | 3,125,594 | — | — |
| Shares issuable upon conversion of 2026 Convertible Notes, as if converted | 5,769,232 | 5,769,232 | 5,769,232 |
| Weighted average common shares outstanding, diluted | 85,446,886 | 82,598,666 | 82,086,795 |
| | | | |
| Net loss per share attributable to common stockholders, diluted | $ (0.23) | $ (0.73) | $ (0.75) |

The Company excluded the following common stock equivalents and restricted stock units, outstanding as of September 30, 2022 and 2021, from the computation of diluted net loss per share for the nine months ended September 30, 2022 and 2021 because they had an anti-dilutive impact.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Options to purchase common stock | 13,795,937 | 3,226,777 | 13,795,937 | 10,948,312 |
| Restricted stock units | 1,050,339 | — | 1,050,339 | — |
| | 14,846,276 | 3,226,777 | 14,846,276 | 10,948,312 |

**13. Stock-Based Awards**

***2021 Stock Incentive Plan***

The 2021 Stock Incentive Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units ("RSUs"), stock appreciation rights and other stock-based awards. Upon its adoption, the number of shares of common stock authorized for issuance under the 2021 Stock Incentive Plan equaled the total of 6,000,000 shares of common stock plus up to the sum of 456,334 shares remaining available for grant under the 2014 Stock Incentive Plan (the "2014 Plan") as of immediately prior to the effective date of the 2021 Plan and 9,766,336 shares subject to awards granted under the 2014 Plan or the Company's 2006 Stock Incentive Plan, which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject to certain limitations).

At the Company's 2022 Annual Meeting of Stockholders held on June 16, 2022, the Company's stockholders approved an amendment to the 2021 Stock Incentive Plan (as amended, the "2021 Plan") to increase the number of shares of common stock authorized for issuance under the 2021 Plan by 3,600,000 shares. As of September 30, 2022, 5,799,291 shares of common stock remained available for issuance under the 2021 Plan.

***Stock Option Awards for the Three and Nine Months Ended September 30, 2022***

During the three and nine months ended September 30, 2022, the Company granted options to purchase 212,150 and 3,631,403 shares of common stock, at a weighted exercise price of $4.90 and $5.01, respectively, per share under the 2021 Plan.

***RSU Awards for the Three and Nine Months Ended September 30, 2022***

During the three and nine months ended September 30, 2022, the Company granted 67,116 and 1,121,999 RSUs, respectively, under the 2021 Plan. Each RSU is equivalent to one share of common stock upon vesting. Each RSU award vests on an annual basis over a three-year period. Holders of RSUs are not entitled to vote on any matters and are not entitled to dividends. The Company has determined the fair value of each RSU based on the closing price of the Company's common stock on the date of grant and recognizes the compensation expense using the straight-line method over the service period, which coincides with the vesting period.

**Stock-based Compensation Expense**

The Company recorded stock-based compensation expense related to stock options and RSUs in the following expense categories of its condensed consolidated statements of operations:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Research and development | $ 1,060 | $ 871 | $ 3,157 | $ 2,754 |
| Selling and marketing | 1,169 | 1,064 | 3,499 | 2,947 |
| General and administrative | 2,011 | 1,823 | 6,074 | 5,435 |
| | $ 4,240 | $ 3,758 | $ 12,730 | $ 11,136 |

As of September 30, 2022, the Company had an aggregate of $22,546 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.6 years.

**14. Related Party Transactions**

In November 2020, the Company engaged Specialty Pharma Consulting, LLC (“Specialty Pharma”), an entity affiliated with Kevin Coughenour, to provide services for quality engineering and validation activities in the ordinary course of business. Mr. Coughenour is married to the Company’s former Chief Operating Officer Patricia Kitchen. The Company incurred fees for quality engineering and validation activities rendered by Specialty Pharma of $0 and $155, for the three and nine months ended September 30, 2021, respectively. On April 26, 2021, the Company and Specialty Pharma terminated their relationship.

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP (“WilmerHale”) to provide certain legal services to the Company. The Company's Chief Business Officer’s sister is a managing partner at WilmerHale, who has not participated in providing legal services to the Company. The Company incurred fees for legal services rendered by WilmerHale of approximately $342 and $876 for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022 and December 31, 2021, there was $77 and $119 recorded in accounts payable for WilmerHale. As of September 30, 2022 and December 31, 2021, there was $157 and $68 recorded in accrued expenses for WilmerHale.

**15. Common Stock**

On August 9, 2021, the Company and Jefferies LLC (“Jefferies”) entered into an Open Market Sale Agreement (the “2021 Sales Agreement”) under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $100,000 from time to time through Jefferies, acting as agent. As of November 4, 2022, the Company has not sold any shares of common stock under the 2021 Sales Agreement.

**16. Subsequent Events**

On October 18, 2022, the Company exercised its option to extend the existing operating lease for its manufacturing space located at 36 Crosby Drive in Bedford, Massachusetts (19,786 square feet), which would otherwise have expired on July 31, 2023, by an additional five-year term, resulting in a new expiration date of July 31, 2028. Under the terms of the existing lease, rent for the five-year extension period will be based on the current fair market rent for comparable space in the building and in other similar buildings in the same rental market as of August 1, 2023, the commencement date of the additional five-year term. Because rent has not yet been determined, the Company cannot make a reliable estimate of the financial effect of this event.

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.*

***Overview***

We are a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using our proprietary bioresorbable hydrogel-based formulation technology. Core to our strategy is to continue to (i) build upon our experience commercializing ophthalmology products that can be administered primarily in the surgical and/or office settings and (ii) develop a clinical pipeline of innovative ophthalmology products that address large areas of unmet need.

We currently have one FDA-approved product in commercialization in the United States, DEXTENZA®, an intracanalicular insert for the treatment of both post-surgical ocular inflammation and pain and ocular itching associated with allergic conjunctivitis. We also have an additional FDA-approved product, ReSure Sealant, an ophthalmic device designed to prevent wound leaks in corneal incisions following cataract surgery that is not commercially available in the United States and that we are not currently manufacturing. We also have product candidates in preclinical and clinical development designed to utilize our proprietary, bioresorbable hydrogel technology to treat retinal diseases including wet age-related macular degeneration, or wet AMD, diabetic retinopathy, and other retinal diseases; glaucoma or ocular hypertension; and ocular surface diseases and conditions, including dry eye disease. In addition, we have preclinical programs to develop a gene delivery therapy product candidate for targeting inherited and acquired ocular diseases and to develop a product candidate for the treatment of dry age-related macular degeneration, or dry AMD, through complement inhibition.

Our current products and product candidates in clinical development incorporate therapeutic agents that have previously received regulatory approval from the FDA, including small molecules and proteins, into our proprietary bioresorbable hydrogel-based formulation technology in our internal drug development activities, with the goal of providing local programmed-release to tailor the duration and amount of drug to be delivered to the eye. We believe that our local programmed-release drug delivery technology has the potential to treat conditions and diseases of both the front and the back of the eye and can be administered through a range of different modalities including intravitreal implants, suprachoroidal implants, intracameral implants and intracanalicular inserts.

Our core pipeline assets include four programs in clinical development:

- OTX-TKI, an axitinib intravitreal implant being developed for the treatment of wet AMD, diabetic retinopathy and other retinal diseases;
- OTX-TIC, a travoprost intracameral implant being developed for the reduction of intraocular pressure, or IOP, in patients with primary open-angle glaucoma or ocular hypertension;
- OTX-DED, a dexamethasone intracanalicular insert being developed for the short-term treatment of the signs and symptoms of dry eye disease; and
- OTX-CSI, a cyclosporine intracanalicular insert being developed for the chronic treatment of dry eye disease.

***Commercial Portfolio***

***Post-Surgical Ocular Inflammation and Pain***
***Ocular Itching Associated with Allergic Conjunctivitis***

*DEXTENZA (dexamethasone ophthalmic insert) 0.4mg for intracanalicular use for the Treatment of Post-Surgical Ocular Inflammation and Pain or Ocular Itching Associated with Allergic Conjunctivitis*

DEXTENZA incorporates the FDA-approved corticosteroid dexamethasone as a preservative-free active pharmaceutical ingredient into a hydrogel, drug-eluting intracanalicular insert for the treatment of post-surgical ocular inflammation and pain. The FDA approved a new drug application, or NDA, for DEXTENZA for the treatment of post-surgical ocular pain in November 2018 and approved a supplemental new drug application, or sNDA, for DEXTENZA for the treatment of post-surgical ocular inflammation in June 2019. In July 2019, we commercially launched DEXTENZA in the United States. DEXTENZA is the first FDA-approved, physician-administered intracanalicular insert delivering dexamethasone to treat post-surgical ocular inflammation and pain for up to 30 days with a single administration.

In October 2021, the FDA approved an sNDA for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional indication. With the approval, DEXTENZA is the first FDA-approved, physician-administered intracanalicular insert for the delivery of a preservative-free drug for the treatment of ocular itching associated with allergic conjunctivitis with a single administration for up to 30 days. DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis also represents our first indication approved to be administered in an ophthalmology or optometric office during a routine, non-surgical appointment. In the first quarter of 2022, we commercially launched DEXTENZA in the United States for the treatment of ocular itching associated with allergic conjunctivitis. We have established a separate, smaller office sales force team, dedicated to calling on ophthalmology and optometric offices which is comprised of Key Account Managers and supported by the field reimbursement team. This dedicated sales force could also support our broader pipeline of product candidates in the future, as we believe certain of our other product candidates, if approved, would be primarily used in the office setting.

In November of 2022, the Centers for Medicare & Medicaid Services issued the calendar year 2023 hospital outpatient prospective payment system (OPPS) rules, confirming that DEXTENZA will continue to be separately payable in ambulatory surgery centers under the non-opioid supply provision through 2023. In addition, physician reimbursement for the insertion of DEXTENZA remains available under the product's Category 1 code, which became effective January 1, 2022, ensuring more reliable payment to physicians for DEXTENZA placement across all payer types and in all settings of care.

We are currently conducting one clinical trial of DEXTENZA as a post-approval requirement of the FDA in accordance with the Pediatric Research Equity Act of 2003, in connection with the FDA's approval of DEXTENZA. In September 2020, we announced that we had dosed the first pediatric subjects in a U.S.-based, randomized, multicenter Phase 3 clinical trial evaluating DEXTENZA for the treatment of post-surgical ocular inflammation and pain in children following cataract surgery. We intend to enroll approximately 60 subjects in this clinical trial. It is designed to evaluate the safety and biological activity of DEXTENZA compared to an active control, prednisolone acetate suspension eye drops, for the treatment of inflammation and pain following ocular surgery for pediatric cataract in children between zero and five years of age. The primary endpoint is the absence of pain at day eight post-treatment as measured by a FLACC (Face, Legs, Activity, Cry, Consolability) score of zero. Enrollment is ongoing. The FDA has agreed that this Phase 3 clinical trial evaluating DEXTENZA for the treatment of post-surgical ocular inflammation and pain in children following cataract surgery will also satisfy the post-approval requirement for a pediatric trial as it relates to the approval for ocular itching associated with allergic conjunctivitis.

***Prevention of Wound Leaks Following Cataract Surgery***

*ReSure Sealant*

In 2014, we commercially launched ReSure Sealant in the United States as a device approved to prevent wound leaks in corneal incisions following cataract surgery. In the pivotal clinical trials that formed the basis for FDA approval, ReSure Sealant provided superior wound closure and a better safety profile than sutured closure.

We have received only limited revenues from ReSure Sealant to date as the product is only used in a minority of cataract surgeries and, currently, there is no direct separate reimbursement for the product—meaning ReSure Sealant is only reimbursed as part of a bundled payment for the associated surgery. As of the fourth quarter of 2021, we suspended the production of ReSure Sealant in order to focus our manufacturing resources on the commercialization of DEXTENZA. Currently, ReSure Sealant is not commercially available in the United States.

***Clinical Portfolio***

***Retinal Disease Programs***

*OTX-TKI (axitinib intravitreal implant)*

Our product candidate OTX-TKI is a preformed, bioresorbable hydrogel fiber implant incorporating axitinib, a small molecule tyrosine kinase inhibitor, or TKI, with anti-angiogenic properties delivered by intravitreal injection and designed for a duration of six months or longer. We are conducting a Phase 1 clinical trial of OTX-TKI in Australia and a Phase 1 clinical trial in the United States.

Our Phase 1 clinical trial of OTX-TKI in Australia is comprised of four cohorts consisting of subjects with pre-existing intraretinal and/or subretinal fluid: a lower dose cohort of 200 µg with six subjects; a higher dose cohort of 400 µg with seven subjects; a third cohort with two parallel arms, one arm of six subjects receiving a concomitant anti-VEGF injection with 400 µg of OTX-TKI and the other arm of six subjects receiving a 600 µg of OTX-TKI with no anti-VEGF injection; and a fourth cohort with two parallel arms, one arm of six subjects receiving a 600 µg single implant of OTX-TKI and the other arm of six subjects receiving a 600 µg single implant of OTX-TKI with anti-VEGF injection. In this trial, we are evaluating whether OTX-TKI can reduce existing fluid levels. This trial's enrollment is complete. Following completion of the trial, we plan to continue to follow subjects at least until their respective seventeen month anniversaries of initial dosing, in accordance with the clinical trial protocol.

At the Angiogenesis, Exudation, and Degeneration 2022 Meeting held in February 2022, we presented interim data from the ongoing Phase 1 clinical trial of OTX-TKI for the treatment of wet AMD conducted in Australia. In subjects with subretinal and/or intraretinal fluid due to wet AMD, OTX-TKI was observed to be generally well tolerated. This data also showed a preliminary signal of biological activity as observed by a clinically meaningful decrease in intraretinal and/or subretinal fluid. We observed extended duration of activity of six months or more for over 60% of subjects across all cohorts and for over 80% of subjects in cohort 3a, in which we administered a 600 µg dose. We believe that a six-month duration of activity could represent a compelling drug product profile.

Our Phase 1 clinical trial of OTX-TKI in the United States enrolled a total of 21 subjects at six clinical sites, comprising two arms consisting of subjects previously treated with, and responsive to, a standard of care anti-VEGF therapy: a 16-subject arm receiving 600 µg OTX-TKI in combination with a single anti-VEGF injection at month one and a five-subject arm receiving on-label aflibercept at eight-week intervals. In this trial, we are evaluating how long we are able to maintain subjects without the need for retreatment. This trial was fully enrolled as of February 2022.

In September 2022, we announced interim seven-month data from the ongoing Phase 1 clinical trial of OTX-TKI in the United States. As of the August 24, 2022 data cutoff date, the interim data showed that the single 600 µg OTX-TKI implant was generally well tolerated with a favorable safety profile. There were no drug-related ocular or systemic serious adverse events, or SAEs, observed. One SAE of endophthalmitis was observed in the OTX-TKI arm which occurred following the aflibercept injection required by the clinical trial protocol at month one and was assessed by the investigator as related to the injection procedure. There were no reported adverse events such as elevated IOP, retinal detachment, retinal vasculitis, or implant migration into the anterior chamber observed in the OTX-TKI arm, and no subjects dropped out of either arm.

There was one subject randomized to the OTX-TKI arm who was inadvertently given aflibercept instead of sham injections at the subject's month three and month five visits. Since this subject was not treated according to protocol, the subject was excluded from the analysis of biological activity, which comprised 15 out of the 16 subjects in the OTX-TKI arm and all five subjects in the aflibercept arm, but the subject was included in the safety analysis which comprised all 16 subjects in the OTX-TKI arm and all five subjects in the aflibercept arm.

The interim results showed subjects treated with a single 600 µg OTX-TKI implant demonstrated stable and sustained best corrected visual acuity (BCVA) (mean change from baseline of -1.3 letters) and central subfield thickness (CSFT) (mean change from baseline of +9.2 µm) in the OTX-TKI arm at seven months, which was comparable with the aflibercept arm dosed every eight weeks (mean change from BVCA baseline of -1 letter; mean change from CSFT baseline of +0.4 µm). The data also showed that 80% of subjects in the OTX-TKI arm were rescue-free up to six months and 73% of subjects in the OTX-TKI arm were rescue-free up to seven months.

Four subjects were rescued in the OTX-TKI arm. One subject, the subject who experienced endophthalmitis, was rescued twice. None of these rescues met the preestablished rescue criteria set forth in the clinical trial protocol and were instead initiated at investigator discretion.

We plan to complete our analysis of the interim data from the Phase 1 U.S.-based trial and meet with the FDA to discuss potential future clinical trial requirements. Subject to those discussions, we currently plan to initiate a Phase 2/3 U.S.-based clinical trial to evaluate OTX-TKI for the treatment of wet AMD in the third quarter of 2023. We also plan to continue to follow subjects in the U.S.-based Phase 1 clinical trial at least until their respective one-year anniversaries of initial dosing, in accordance with the clinical trial protocol. In addition, we plan to provide a second data update of the Phase 1 U.S. based clinical trial of OTX-TKI for the treatment of wet AMD at the Angiogenesis, Exudation, and Degeneration 2023 Annual Meeting in February 2023 that we expect will include Month 10 safety and efficacy data.

Given our belief in the potential broad applicability of OTX-TKI to other retinal diseases, we also plan to initiate a Phase 1 U.S.-based clinical trial to evaluate OTX-TKI for the treatment of diabetic retinopathy in the first quarter of 2023. We intend to conduct the Phase 1 clinical trial initially under an existing exploratory IND, or eIND, and anticipate the trial will enroll a total of approximately twenty subjects randomized to either a single 600 µg implant of OTX-TKI or sham control. Assuming positive topline data results from the Phase 1 clinical, and subject to a follow-up meeting with the FDA, we believe we could be in a position to initiate our first Phase 3 pivotal clinical trial of OTX-TKI for the treatment of diabetic retinopathy in the first quarter of 2024.

OTX-TKI is protected by a composition of matter patent, U.S. Patent Number 11,439,592, with an expiration date of March 2041. Additional U.S. and foreign patent applications are pending.

***Glaucoma Program***

*OTX-TIC (travoprost intracameral implant)*

Our product candidate OTX-TIC is a bioresorbable hydrogel implant incorporating travoprost that is designed to be administered by a physician as an intracameral injection with an initial target duration of drug release of four to six months. In the fourth quarter of 2021, we initiated a randomized, double-masked, controlled Phase 2 clinical trial in which we plan to enroll approximately 105 subjects with open-angle glaucoma or ocular hypertension at 15 to 20 sites between three arms of approximately 35 subjects each to evaluate two formulations of OTX-TIC for the treatment of open-angle glaucoma or ocular hypertension in patients compared to DURYSTA™. We dosed the first patient in the first quarter of 2022 and currently expect to disclose topline data in the fourth quarter of 2023.

At the Glaucoma 360 Meeting in February 2022, we presented interim data from a Phase 1 clinical trial evaluating OTX-TIC for the treatment of open-angle glaucoma or ocular hypertension. In this clinical trial, OTX-TIC was observed to cause a clinically meaningful decrease in IOP for six months or longer in patients while preserving corneal health. We believe these results are comparable to the decrease in IOP seen with topical travoprost, the current standard of care, and represent OTX-TIC's potential for a unique and differentiated drug product profile. OTX-TIC was observed to be generally well tolerated with a favorable safety profile to date and endothelial cell counts, pachymetry assessments, and slit lamp examinations in subjects indicated no changes from baseline. As a result, we are developing OTX-TIC for potential chronic or repeat dosing.

***Ocular Surface Disease Programs***

***Dry Eye Disease***

*OTX-DED (dexamethasone intracanalicular insert)*

Our product candidate OTX-DED incorporates the FDA-approved corticosteroid dexamethasone as a preservative-free active pharmaceutical ingredient in a hydrogel, drug-eluting intracanalicular insert. OTX-DED incorporates the same active drug as DEXTENZA but includes a lower dose of the drug, is administered in the office setting as a smaller insert and is designed to release dexamethasone over a period of two to three weeks, compared with up to thirty days in the case of DEXTENZA.

We announced the topline results for a Phase 2 clinical trial evaluating OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease in December 2021. The clinical trial achieved its pre-specified primary endpoint. While the clinical trial was not powered to show statistical significance, the topline results demonstrated a statistically significant change of bulbar conjunctival hyperemia from baseline to day 15 compared to vehicle hydrogel using a central reading photographic assessment in the modified ITT population. Both formulations of OTX-DED were observed to have a favorable safety profile and to be generally well tolerated.

Based on the data from the Phase 2 clinical trial, we intend to conduct a small trial in connection with our efforts to develop an appropriate placebo comparator that may be used in both the OTX-DED and OTX-CSI programs. Specifically, we intend to evaluate the performance of OTX-DED versus placebo inserts, namely fast-dissolving collagen plugs, and no inserts at all, to explain the placebo performance seen in both the OTX-DED and the OTX-CSI Phase 2 trials in which the vehicle hydrogel placebo insert or placebo comparator vehicle remained in the canaliculus longer than anticipated, performing more like an active comparator than a placebo. We currently expect to begin this trial in the first half of 2023.

*OTX-CSI (cyclosporine intracanalicular insert)*

Our product candidate OTX-CSI incorporates the FDA-approved immunomodulator cyclosporine as a preservative-free active pharmaceutical ingredient into a hydrogel, drug-eluting intracanalicular insert. The product candidate is designed for a duration of three to four months for patients suffering from moderate to severe dry eye and to be administered in the office setting as a bioresorbable intracanalicular insert.

We announced topline results from a Phase 2 clinical trial evaluating two different formulations of OTX-CSI for the chronic treatment of dry eye disease in October 2021. The study did not show separation between the OTX-CSI treated subjects (both formulations) and the vehicle hydrogel placebo insert treated subjects for the primary endpoint of increased tear production at 12 weeks. The study did show an improvement compared with baseline in signs of dry eye disease as measured by total corneal fluorescein staining, or CFS, and symptoms of dry eye disease as measured by the Visual Analog Score, or VAS, eye dryness in subjects treated with the OTX-CSI insert (both formulations) starting as early as two weeks after insertion and continuing over the 12 week study period. However, these improvements in OTX-CSI treated subjects were not statistically significant compared with the results of the vehicle insert in subjects with respect to either the signs of dry eye disease as measured by CFS or the symptoms of dry eye disease as measured by VAS eye dryness. Also, the trial results indicated that the durability of the OTX-CSI inserts was shorter than expected. Overall, the OTX-CSI insert (both formulations) was observed to be generally well tolerated with a favorable safety profile to date.

We are continuing formulation work to extend the durability of the OTX-CSI insert and select the most appropriate formulations to move forward.

***AffaMed License Agreement***

In October 2020, we entered into a license agreement and collaboration with AffaMed Therapeutics Limited, or AffaMed, for the development and commercialization of DEXTENZA and OTX-TIC in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations. Under the terms of the agreement, we received an upfront payment of $12 million and became eligible to receive development, regulatory and commercial milestone payments and clinical development support payments of up to $91 million in the aggregate, as

well as royalties from future product sales. In the fourth quarter of 2021, we received a $1 million milestone payment upon the approval by the FDA of an sNDA for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional indication; in the second quarter of 2022, we received another $2 million clinical support payment in connection with dosing the first subject in a Phase 2 clinical trial evaluating OTX-TIC for the treatment of open-angle glaucoma or ocular hypertension. Royalties are tiered and will range from the low teens to low twenty percent range. In return, we agreed to grant AffaMed exclusive rights to develop and commercialize DEXTENZA for the treatment of post-surgical inflammation and pain following ophthalmic surgery and ocular itching in patients with allergic conjunctivitis, and OTX-TIC for the reduction of elevated IOP in patients with primary open-angle glaucoma or ocular hypertension in specified Asian markets. We retain the right to develop and commercialize DEXTENZA and OTX-TIC in all other global markets.

In January 2022, AffaMed announced that it had dosed its first patient in a real-world setting study conducted in China evaluating the safety and efficacy of DEXTENZA® (0.4mg dexamethasone ophthalmic insert) for the treatment of ocular inflammation and pain post-cataract surgery. This prospective, single-arm, real-world trial is designed to assess the safety and efficacy of DEXTENZA for the treatment of ocular inflammation and pain following cataract surgery in approximately 120 patients at the Bo'ao Super Hospital. The trial's primary efficacy endpoint is the absence of anterior chamber cells in the study eye at Day 14, and the key secondary endpoint is the absence of pain in the study eye at Day 8.

In April 2022, AffaMed announced that DEXTENZA has been approved in Macau, China for the treatment of ocular inflammation and pain following ophthalmic surgery. We do not expect that DEXTENZA sales in Macau will result in material revenues to us.

***Mosaic Biosciences Agreement***

In June 2021, we entered into an agreement with Mosaic Biosciences, Inc., or Mosaic, to identify new targets and discover novel therapeutic agents aimed at the treatment of dry AMD. Our collaboration with Mosaic has yielded lead compounds that Mosaic has humanized and is now optimizing for our preclinical complement inhibitor program for the treatment of dry AMD. We believe that product candidates with these compounds have the potential to be best-in-class in the complement space with targeted dosing every three to four months.

***Business Update Regarding COVID-19***

The pandemic caused by an outbreak of a new strain of coronavirus, or the COVID-19 pandemic, that is affecting the U.S. and global economy and financial markets and the related responses of government, businesses and individuals are impacting our employees, patients, customers, communities and business operations. The implementation of travel bans and restrictions, quarantines, shelter-in-place/stay-at-home and social distancing orders and shutdowns, for example, affected our business in 2020 and 2021. During the first nine months of 2022, the COVID-19 pandemic and related employee recruitment and retention challenges for ambulatory surgical centers, or ASCs, and hospital out-patient departments, or HOPDs, slowed the overall pace of cataract procedures performed in the United States, thereby reducing the number of opportunities for ophthalmologists to use DEXTENZA as a treatment for post-surgical ocular inflammation and pain. In addition, recruitment and retention challenges with regards to our own sales force have adversely affected our ability to market DEXTENZA to ophthalmologists and in the office setting. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition and those of our customers, vendors, suppliers, and collaboration partners will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Management continues to actively monitor this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce. For additional information on risks posed by the COVID-19 pandemic, please see "Item 1A — Risk Factors — Risks Related to the Coronavirus Pandemic," included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022.

**Financial Position**

Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our continued commercialization of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and

for the treatment of ocular itching associated with allergic conjunctivitis, and our obtaining marketing approval for and commercializing other products with significant market potential, including OTX-TKI for the treatment of wet AMD, diabetic retinopathy and other retinal diseases, OTX-TIC for the treatment of open-angle glaucoma or ocular hypertension, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, and OTX-CSI for the chronic treatment of dry eye disease. Our net loss was $24.2 million and $55.5 million for the three and nine months ended September 30, 2022, respectively. Our net income was $2.7 million for the three months ended September 30, 2021 and our net loss was $2.7 million for the nine months ended September 30, 2021. As of September 30, 2022, we had an accumulated deficit of $601.3 million.

Our total costs and operating expenses were $33.5 million and $96.7 million for the three and nine months ended September 30, 2022 including $4.7 million and $14.3 million in non-cash stock-based compensation expense and depreciation and amortization expense, respectively. Our total costs and operating expenses were $31.7 million and $91.2 million for the three and nine months ended September 30, 2021 including $4.4 million and $13.0 million in non-cash stock-based compensation expense and depreciation and amortization expense, respectively. Our operating expenses have grown as we continue to commercialize DEXTENZA following its entry into the market in July 2019; pursue the clinical development of OTX-TKI, OTX-TIC, OTX-DED, and OTX-CSI; research and develop other product candidates; and seek marketing approval for any product candidate for which we obtain favorable pivotal clinical trial results. We expect to incur substantial sales and marketing expenses in connection with the ongoing commercialization of DEXTENZA and that of any other product candidate for which we may receive approval.

Although we expect to continue to generate revenue from sales of DEXTENZA, we will need to obtain substantial additional funding to support our continuing operations and the ongoing commercialization of DEXTENZA. If we are unable to raise capital through equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or commercialization efforts or to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Through September 30, 2022, we have financed our operations primarily through sales of our products, public offerings of our common stock, private placements of our convertible notes, borrowings under credit facilities and private placements of our preferred stock, which has resulted in net proceeds of $641.4 million to us.

In August 2021, we and Jefferies LLC, or Jefferies, entered into an Open Market Sale Agreement, or the 2021 Sales Agreement, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through Jefferies, acting as agent. In connection with entering into the 2021 Sales Agreement, we and Jefferies terminated our prior Open Market Sale Agreement which we had entered into in 2019. As of November 4, 2022, we have not sold any shares of our common stock under the 2021 Sales Agreement.

DEXTENZA and all of our product candidates are designed to be medical-benefit “buy-and-bill” products with associated procedure codes. Products with these characteristics are designed to be attractive not only to physicians, optometrists, and patients but also to the sites of care that participate in utilization. We primarily derive our product revenues from the sale of DEXTENZA in the United States to a network of specialty distributors, who then sell DEXTENZA to ASCs, HOPDs, and ophthalmology and optometric offices. We also sell directly to a small population of ASCs. In addition to distribution agreements with specialty distributors and a limited number of direct agreements with ASCs, we enter into arrangements with government payors that provide for government-mandated rebates and chargebacks with respect to the purchase of DEXTENZA. In-market unit sales figures—unit sales from specialty distributors to ASCs and HOPDs—for July, August and September 2022 were 8,348, 9,410 and 8,649 units, respectively. In-market unit sales for October 2022 were approximately 11,500 units.

Based on our current plans and forecasted expenses, which includes estimates of anticipated cash inflows from DEXTENZA product sales and cash outflows from operating expenses, we believe that our existing cash and cash equivalents of $121.0 million as of September 30, 2022 will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through 2023. This estimate is based on our current operating plan which includes estimates of anticipated cash inflows from DEXTENZA product sales, and cash outflows from both operating expenses and capital expenditures. These estimates are subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues and expenses associated with the commercialization of DEXTENZA, the pace of our research and clinical development programs, and other aspects of

our business. These and other assumptions upon which we have based our estimate may prove to be wrong, and we could use our capital resources sooner than we currently expect and would therefore need to raise additional capital to support our ongoing operations or adjust our plans accordingly. See "—Liquidity and Capital Resources."

**Financial Operations Overview**

***Revenue***

In June 2019, we began to recognize revenue from the sales of DEXTENZA for the treatment of post-surgical ocular inflammation and pain. Following the FDA's approval of our sNDA in October 2021, we launched DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, our first in-office indication. We began to recognize revenue from the sales of ReSure Sealant for the prevention of wound leaks in corneal incisions following cataract surgery in 2014, although we have received only limited revenues from ReSure Sealant to date. As of the fourth quarter of 2021, we suspended the production of ReSure Sealant in order to focus our manufacturing resources on the commercialization of DEXTENZA.

For the three and nine months ended September 30, 2022, three specialty distributor customers accounted for 42%, 30% and 14%, and 41%, 27% and 18%, respectively, of our total gross product revenue, and no other customer accounted for more than 10% of our total gross product revenue. At September 30, 2022, the three specialty distributor customers accounted for 44%, 30%, and 15% of our total accounts receivable, and no other customer accounted for more than 10% of our total accounts receivable at September 30, 2022.

For the three months and nine months ended September 30, 2021, three specialty distributor customers accounted for 44%, 28%, and 16%, and 44%, 26% and 15%, respectively, of our total gross product revenue, and no other customer accounted for more than 10% of our total gross product revenue.

At December 31, 2021, three specialty distributor customers accounted for 42%, 26% and 21% of our total accounts receivable. No other customer accounted for more than 10% of our accounts receivable at December 31, 2021.

***Operating Expenses***

*Cost of Product Revenue*

Cost of product revenue consists primarily of costs of DEXTENZA product revenue, which include:

- Direct materials costs;
- Royalties;
- Direct labor, which includes employee-related expenses, including salaries, related benefits and payroll taxes, and stock-based compensation expense for employees engaged in the production process;
- Manufacturing overhead costs, which includes rent, depreciation, and indirect labor costs associated with the production process;
- Transportation costs; and
- Cost of scrap material.

*Research and Development Expenses*

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

- employee-related expenses, including salaries, related benefits and payroll taxes, travel and stock-based compensation expense for employees engaged in research and development, clinical and regulatory and other related functions;

- expenses incurred in connection with the clinical trials of our product candidates, including with the investigative sites that conduct our clinical trials and under agreements with contract research organizations, or CROs;
- expenses relating to regulatory activities, including filing fees paid to the FDA for our submissions for product approvals;
- expenses associated with developing our pre-commercial manufacturing capabilities and manufacturing clinical study materials;
- ongoing research and development activities relating to our core bioresorbable hydrogel technology and improvements to this technology;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs relating to the supply and manufacturing of product inventory, prior to approval by the FDA or other regulatory agencies of our products; and
- expenses associated with preclinical development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials and regulatory fees. We do not allocate employee and contractor-related costs, costs associated with our platform technology, costs related to manufacturing or purchasing clinical trial materials, and facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified. We use internal resources in combination with third-party CROs, including clinical monitors and clinical research associates, to manage our clinical trials, monitor subject enrollment and perform data analysis for many of our clinical trials. These employees work across multiple development programs and, therefore, we do not track their costs by program.

The successful development and commercialization of our products or product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the timing, receipt and terms of any marketing approvals;
- the efficacy and potential advantages of our products or product candidates compared to alternative treatments, including any standard of care;
- the market acceptance of our products or product candidates; and
- significant and changing government regulation.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical and preclinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time

on the completion of clinical development of that product candidate. We anticipate that our research and development expenses will increase in the future as we support our continued development of our product candidates.

*General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, information technology, human resources, legal and administrative functions. General and administrative expenses also include insurance, facility-related costs and professional fees, costs associated with intellectual property, consulting and accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we support our continued development and commercialization of our product candidates. We also anticipate that we will continue to incur increased accounting, audit, legal, intellectual property, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

*Selling and Marketing Expenses*

Selling and marketing expenses consist primarily of salaries and related costs for personnel in selling and marketing functions as well as consulting, advertising and promotion costs. Selling and marketing expenses for DEXTENZA increased in 2021 in connection with the continued commercialization of DEXTENZA for the treatment of ocular inflammation and pain, focused on ASCs and HOPDs, and the preparations for the commercial launch of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis focused on the offices of ophthalmologists and optometrists. We anticipate that our selling and marketing expenses associated with DEXTENZA will continue to increase, particularly as we continue to grow our salesforce supporting DEXTENZA in 2022 and beyond and incur additional marketing expenses in connection with the commercialization of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis.

***Other Income (Expense)***

*Interest Expense*. Interest expense is incurred on our debt. In June 2021, we amended and restated our credit and security agreement, which we refer to as our Credit Agreement, to increase the aggregate principal amount borrowed under our credit facility, which we refer to as our Credit Facility, to $25.0 million, extend the interest-only payment period to May 1, 2024, and extend the maturity date to November 2025. In the event we achieve certain milestones under the Credit Agreement, we have the right to extend through April 1, 2026.

In March 2019, we issued $37.5 million of unsecured senior subordinated convertible notes, or the 2026 Convertible Notes. The 2026 Convertible Notes accrue interest at an annual rate of 6% of the outstanding principal amount, payable in cash at maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed.

*Change in Fair Value of Derivative Liability.* In 2019, in connection with the issuance of our 2026 Convertible Notes, we identified an embedded derivative liability, which we are required to measure at fair value at inception and then at the end of each reporting period until the embedded derivative is settled. The changes in fair value are recorded through the condensed consolidated statement of operations and comprehensive income (loss) and are presented under the caption change in fair value of derivative liability.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies, which include those related to revenue recognition and our derivative liability, are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022 and in the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. There have been no significant changes to our critical accounting policies since the beginning of this fiscal year.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2022 and 2021***

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

| | Three Months Ended September 30, | | Increase (Decrease) |
|---|---|---|---|
| | 2022 | 2021 | |
| | (in thousands) | | |
| Revenue: | | | |
| Product revenue, net | $ 11,913 | $ 12,153 | $ (240) |
| Collaboration revenue | 52 | — | 52 |
| Total revenue, net | 11,965 | 12,153 | (188) |
| Costs and operating expenses: | | | |
| Cost of product revenue | 1,073 | 1,310 | (237) |
| Research and development | 13,719 | 12,719 | 1,000 |
| Selling and marketing | 10,186 | 9,576 | 610 |
| General and administrative | 8,531 | 8,077 | 454 |
| Total costs and operating expenses | 33,509 | 31,682 | 1,827 |
| Loss from operations | (21,544) | (19,529) | (2,015) |
| Other income: | | | |
| Interest income | 285 | 7 | 278 |
| Interest expense | (1,797) | (1,658) | (139) |
| Change in fair value of derivative liability | (1,133) | 23,837 | (24,970) |
| Other income (expense), net | 1 | — | 1 |
| Total other income, net | (2,644) | 22,186 | (24,830) |
| Net (loss) income | $ (24,188) | $ 2,657 | $ (26,845) |

*Gross-to-Net Deductions*

We record DEXTENZA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. Our total gross-to-net provisions for the three months ended September 30, 2022 and 2021 were 24.3% and 22.2%, respectively, of gross DEXTENZA product sales.

*Net Revenue*

We generated $11.9 million of net product revenue during the three months ended September 30, 2022 from sales of our products, all of which was attributable to sales of DEXTENZA. We generated $12.2 million of net product revenue during the three months ended September 30, 2021 from sales of our products, of which $11.9 million was attributable to sales of DEXTENZA and $0.3 million was attributable to sales of ReSure Sealant. We believe that DEXTENZA net product revenues in the third quarter of 2022 were adversely affected by recruitment and retention challenges at ASCs and HOPDs, recruitment and retention challenges among our sales force and a reduction in the physician payment for the insertion of DEXTENZA when our procedure code was converted from a T-code into a category 1 code effective January 1, 2022.

*Collaboration Revenue*

We recognized $0.1 million of collaboration revenue related to the performance obligation under our license agreement with AffaMed to conduct a Phase 2 clinical trial of OTX-TIC during the three months ended September 30, 2022. We recognize collaboration revenue based on a cost-to-cost method. There was no collaboration revenue for the three months ended September 30, 2021.

*Research and Development Expenses*

| | Three Months Ended September 30, | | Increase (Decrease) |
|---|---|---|---|
| | 2022 | 2021 | |
| | (in thousands) | | |
| Direct research and development expenses by program: | | | |
| OTX-TKI for wet AMD | $ 1,472 | $ 572 | $ 900 |
| OTX-TIC for glaucoma or ocular hypertension | 798 | 755 | 43 |
| OTX-CSI for treatment of dry eye disease | 48 | 832 | (784) |
| OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease | 10 | 1,037 | (1,027) |
| DEXTENZA for post-surgical ocular inflammation and pain | 457 | 445 | 12 |
| DEXTENZA for ocular itching associated with allergic conjunctivitis | — | 2 | (2) |
| Preclinical programs | 604 | 217 | 387 |
| Unallocated expenses: | | | |
| Personnel costs | 6,204 | 5,373 | 831 |
| All other costs | 4,126 | 3,486 | 640 |
| Total research and development expenses | $ 13,719 | $ 12,719 | $ 1,000 |

Research and development expenses were $13.7 million for the three months ended September 30, 2022, compared to $12.7 million for the three months ended September 30, 2021. The increase of $1.0 million was primarily due to an increase of $1.5 million in unallocated expenses offset by a decrease of $0.5 million in clinical related programs. For the three months ended September 30, 2022, we incurred $3.4 million in direct research and development expenses for our products and product candidates compared to $3.9 million for the three months ended September 30, 2021. The decrease of $0.5 million is related to timing and conduct of our various clinical trials for our product candidates and development activities related to our preclinical programs. We expect that clinical trial expenses will increase for our product candidates, including OTX-TKI due to the ongoing Phase 1 clinical trial in the United States for the treatment of wet AMD, our planned Phase 2 clinical trial in the United States for the treatment of wet AMD, and our planned Phase 1 clinical in the United States for the treatment of diabetic retinopathy, and OTX-TIC due to the ongoing Phase 2 clinical trial, and for DEXTENZA due to the ongoing Phase 3 clinical trial to evaluate DEXTENZA in pediatric subjects following cataract surgery in accordance with the FDA's post-approval requirement. In addition, we have adopted a plan to progress the development of OTX-CSI, including formulation work to improve product retention. We are also planning to conduct a small trial in connection with our efforts to develop an appropriate placebo comparator that may be used in both the OTX-DED and OTX-CSI programs.

*Selling and Marketing Expenses*

| | Three Months Ended September 30, 2022 | 2021 | Increase (Decrease) |
|---|---|---|---|
| | (in thousands) | | |
| Personnel related (including stock-based compensation) | $ 6,907 | $ 6,173 | $ 734 |
| Professional fees | 2,170 | 2,114 | 56 |
| Facility related and other | 1,109 | 1,289 | (180) |
| Total selling and marketing expenses | $ 10,186 | $ 9,576 | $ 610 |

Selling and marketing expenses were $10.2 million for the three months ended September 30, 2022, compared to $9.6 million for the three months ended September 30, 2021. The increase of $0.6 million was primarily due to an increase of $0.7 million in personnel related costs, including stock-based compensation due to the expansion of the commercial workforce to support DEXTENZA.

We expect our selling and marketing expenses to increase in the remainder of 2022 and beyond as we continue to support the commercialization of DEXTENZA.

*General and Administrative Expenses*

| | Three Months Ended September 30, 2022 | 2021 | Increase (Decrease) |
|---|---|---|---|
| | (in thousands) | | |
| Personnel related (including stock-based compensation) | $ 4,727 | $ 4,315 | $ 412 |
| Professional fees | 3,105 | 3,005 | 100 |
| Facility related and other | 699 | 757 | (58) |
| Total general and administrative expenses | $ 8,531 | $ 8,077 | $ 454 |

General and administrative expenses were $8.5 million for the three months ended September 30, 2022, compared to $8.1 million for the three months ended September 30, 2021, primarily due to an increase of $0.4 million personnel related costs, including stock-based compensation.

*Other Income (Expense), Net*

Other income, net was $2.6 million for the three months ended September 30, 2022, compared to other expense, net gain was $22.2 million for the three months ended September 30, 2021. The change of $24.8 million was due primarily to the change in fair value of the derivative liability associated with the 2026 Convertible Notes of $25.0 million due primarily to a decrease in our common stock price from July 1, 2022 to September 30, 2022 as compared to the prior period.

***Comparison of the Nine Months Ended September 30, 2022 and 2021***

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

| | Nine Months Ended September 30, | | Increase (Decrease) |
|---|---|---|---|
| | 2022 | 2021 | |
| | (in thousands) | | |
| Revenue: | | | |
| Product revenue, net | $ 36,555 | $ 31,214 | $ 5,341 |
| Collaboration revenue | 864 | — | 864 |
| Total revenue, net | 37,419 | 31,214 | 6,205 |
| Costs and operating expenses: | | | |
| Cost of product revenue | 3,528 | 3,298 | 230 |
| Research and development | 39,919 | 37,505 | 2,414 |
| Selling and marketing | 29,390 | 26,054 | 3,336 |
| General and administrative | 23,875 | 24,345 | (470) |
| Total costs and operating expenses | 96,712 | 91,202 | 5,510 |
| Loss from operations | (59,293) | (59,988) | 695 |
| Other income (expense): | | | |
| Interest income | 375 | 27 | 348 |
| Interest expense | (5,175) | (4,991) | (184) |
| Change in fair value of derivative liability | 8,598 | 62,249 | (53,651) |
| Other income (expense), net | (1) | — | (1) |
| Total other income (expense), net | 3,797 | 57,285 | (53,488) |
| Net loss | $ (55,496) | $ (2,703) | $ (52,793) |

*Gross-to-Net Deductions*

We record DEXTENZA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. Our total gross-to-net provisions for the nine months ended September 30, 2022 and 2021 were 23.1% and 24.2%, respectively, of gross DEXTENZA product sales.

*Net Revenue*

During the nine months ended September 30, 2022, we generated $36.6 million in net product revenue from sales of our products, all of which was attributable to sales of DEXTENZA. During the nine months ended September 30, 2021, we generated $31.2 million of net revenue from sales of our products, of which $29.7 million was attributable to sales of DEXTENZA and $1.5 million was attributable to sales of ReSure Sealant. We believe the growth in revenue for DEXTENZA was primarily due to increased market acceptance and our ongoing commercialization efforts.

*Collaboration Revenue*

We recognized $0.9 million of collaboration revenue related to the performance obligation under our license agreement with AffaMed to conduct a Phase 2 clinical trial of OTX-TIC during the nine months ended September 30, 2022. We recognize collaboration revenue based on a cost-to-cost method. There was no collaboration revenue for the nine months ended September 30, 2021.

*Research and Development Expenses*

| | Nine Months Ended September 30, 2022 | Nine Months Ended September 30, 2021 | Increase (Decrease) |
|---|---|---|---|
| | | (in thousands) | |
| Direct research and development expenses by program: | | | |
| OTX-TKI for wet AMD | $ 4,016 | $ 3,655 | $ 361 |
| OTX-TIC for glaucoma or ocular hypertension | 1,988 | 2,259 | (271) |
| OTX-CSI for treatment of dry eye disease | 189 | 2,729 | (2,540) |
| OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease | 317 | 3,063 | (2,746) |
| DEXTENZA for post-surgical ocular inflammation and pain | 1,255 | 1,228 | 27 |
| DEXTENZA for ocular itching associated with allergic conjunctivitis | 21 | 78 | (57) |
| ReSure Sealant | — | 59 | (59) |
| Preclinical programs | 1,341 | 688 | 653 |
| Unallocated expenses: | | | |
| Personnel costs | 19,067 | 15,342 | 3,725 |
| All other costs | 11,725 | 8,404 | 3,321 |
| Total research and development expenses | $ 39,919 | $ 37,505 | $ 2,414 |

Research and development expenses were $39.9 million for the nine months ended September 30, 2022, compared to $37.5 million for the nine months ended September 30, 2021. The increase of $2.4 million was primarily due to an increase of $7.0 million in unallocated expenses and offset by a decrease of $4.7 million in clinical related programs. For the nine months ended September 30, 2022, we incurred $9.1 million in direct research and development expenses for our products and product candidates compared to $13.8 million for the nine months ended September 30, 2021. The decrease of $4.7 million is related to timing and start of our various clinical trials for our product candidates and development activities related to our preclinical programs. We expect that clinical trial expenses will increase for our product candidates, including OTX-TKI due to the ongoing Phase 1 clinical trial in the United States for the treatment of wet AMD, our planned Phase 2 clinical trial in the United States for the treatment of wet AMD and our planned Phase 1 clinical in the United States for the treatment of diabetic retinopathy, and OTX-TIC due to the ongoing Phase 2 clinical trial, and for DEXTENZA due to the ongoing Phase 3 clinical trial to evaluate DEXTENZA in pediatric subjects following cataract surgery in accordance with the FDA's post-approval requirement. We are also planning to conduct a small trial in connection with our efforts to develop an appropriate placebo comparator that may be used in both the OTX-DED and OTX-CSI programs.

*Selling and Marketing Expenses*

| | Nine Months Ended September 30, 2022 | Nine Months Ended September 30, 2021 | Increase (Decrease) |
|---|---|---|---|
| | | (in thousands) | |
| Personnel related (including stock-based compensation) | $ 19,487 | $ 17,384 | $ 2,103 |
| Professional fees | 6,875 | 5,544 | 1,331 |
| Facility related and other | 3,028 | 3,126 | (98) |
| Total selling and marketing expenses | $ 29,390 | $ 26,054 | $ 3,336 |

Selling and marketing expenses were $29.4 million for the nine months ended September 30, 2022, compared to $26.1 million for the nine months ended September 30, 2021. The increase of $3.3 million was primarily due to increases of $2.1 million in personnel costs with the expansion of the commercial workforce to support DEXTENZA and $1.3 million in professional fees related to trade shows, conferences and advertising fees.

*General and Administrative Expenses*

| | Nine Months Ended September 30, | | Increase (Decrease) |
|---|---|---|---|
| | 2022 | 2021 | |
| | | (in thousands) | |
| Personnel related (including stock-based compensation) | $ 13,844 | $ 12,720 | $ 1,124 |
| Professional fees | 8,659 | 9,716 | (1,057) |
| Facility related and other | 1,372 | 1,909 | (537) |
| Total general and administrative expenses | $ 23,875 | $ 24,345 | $ (470) |

General and administrative expenses were $23.9 million for the nine months ended September 30, 2022, compared to $24.3 million for the nine months ended September 30, 2021. The decrease of $0.5 million was primarily due to a decrease of $1.1 million in professional fees primarily related to legal fees and other professional service costs and $0.5 million in facility related and other costs offset by an increase of $1.1 million of personnel related costs, including stock-based compensation.

*Other Income (Expense), Net*

Other income, net was $3.8 million for the nine months ended September 30, 2022, compared to $57.3 million other income, net for the nine months ended September 30, 2021. The decrease of $53.5 million was due primarily to the change in fair value of the derivative liability associated with the 2026 Convertible Notes of $53.7 million.

**Liquidity and Capital Resources**

We have a history of incurring significant operating losses. Our net loss was $24.2 million for the three months ended September 30, 2022, primarily due to a loss from operations of $21.5 million, net interest expense of $1.5 million and a change of $1.1 million in the fair value of our derivative liability related to unsecured senior subordinated convertible notes, or the 2026 Convertible Notes, during the period. Our net loss was $55.5 million for the nine months ended September 30, 2022, primarily due to a loss from operations of $59.3 million offset by a change of $8.6 million in the fair value of our derivative liability related to the 2026 Convertible Notes during the period. Our net loss was $2.7 million for the nine months ended September 30, 2021 primarily due to a loss from operations of $60.0 million offset by a change of $62.2 million in the fair value of our derivative liability related to the 2026 Convertible Notes during the period. Our net losses were $6.6 million and $155.6 million for the years ended December 31, 2021 and 2020, respectively. As of September 30, 2022, we had an accumulated deficit of $601.3 million.

We commercially launched DEXTENZA for the treatment of post-surgical ocular inflammation and pain in July 2019, and we commercially launched DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis in the first quarter of 2022. All of our product candidates are in various phases of clinical and preclinical development. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our continued commercialization of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis and our obtaining marketing approval for and commercializing other products with significant market potential, including OTX-TKI for the treatment of wet AMD, diabetic retinopathy and other retinal diseases, OTX-TIC for the treatment of open-angle glaucoma or ocular hypertension, and OTX-DED and OTX-CSI for the treatment of dry eye disease. We believe that recruitment and retention challenges at ASCs and HOPDs and recruitment and retention challenges among our sales force have impacted revenue for the first nine months of 2022, and we anticipate that such challenges may continue beyond the end of 2022.

Under our Credit Agreement, we have a term loan in the aggregate principal amount of approximately $20.8 million, which was rolled over from our prior borrowings under our Credit Facility, and an additional term loan in the principal amount of approximately $4.2 million. We refer to these term loans together as the Term Loans. The aggregate principal amount of the Term Loans available under the Credit Facility, or the Total Credit Facility Amount, is $25.0 million, the entirety of which was drawn at the closing of the most recent amendment to our Credit Facility in June 2021. As of September 30, 2022, the interest rate was 9.31%. Under the current terms of our Credit Facility, we are permitted to make interest-only payments on the Term Loans on a monthly basis until May 1, 2024. Thereafter, in addition to the monthly interest payments, we are required to make principal payments on the Term Loans in accordance with the amortization schedules set forth in the Credit Agreement. Remaining unpaid principal and accrued interest outstanding

on the maturity date is due on the maturity date, which shall be November 30, 2025, unless we are able to provide the Administrative Agent evidence reasonably satisfactory to it, by November 15, 2025, that the outstanding principal amount of the 2026 Convertible Notes has been converted into equity interests of ours and that such indebtedness is otherwise indefeasibly satisfied in full, in which case the term is automatically extended until April 1, 2026.

In March 2019, we issued $37.5 million of the 2026 Convertible Notes. The 2026 Convertible Notes accrue interest at an annual rate of 6% of the outstanding principal amount, payable at maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed. The holders of the 2026 Convertible Notes may convert all or part of the outstanding principal amount of their 2026 Convertible Notes into shares of our common stock, par value $0.0001 per share, prior to maturity and provided that no conversion results in a holder beneficially owning more than 19.99% of our issued and outstanding common stock. The conversion rate is initially 153.8462 shares of our common stock per $1,000 principal amount of the 2026 Convertible Notes, which is equivalent to an initial conversion price of $6.50 per share. The conversion rate is subject to adjustment in customary circumstances such as stock splits or similar changes to our capitalization, none of which have occurred to date.

Through September 30, 2022, we have financed our operations primarily through sales of our products, private placements of our preferred stock, public offerings of our common stock, private placements of our convertible notes and borrowings under credit facilities, which has resulted in net proceeds of $641.4 million to us.

As of September 30, 2022, we had cash and cash equivalents of $121.0 million; outstanding debt of $25.2 million, net of unamortized discount; and the 2026 Convertible Notes with $37.5 million of aggregate principal amount, plus accrued interest of $8.1 million.

***Cash Flows***

Based on our current plans and forecasted expenses, which includes estimates related to anticipated cash inflows from DEXTENZA product sales and cash outflows from operating expenses, we believe that our existing cash and cash equivalents, as of September 30, 2022, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

The following table summarizes our sources and uses of cash for each of the periods presented:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Cash used in operating activities | $ (42,645) | $ (50,397) |
| Cash used in investing activities | (1,565) | (563) |
| Cash provided by financing activities | 996 | 2,184 |
| Net decrease in cash and cash equivalents | $ (43,214) | $ (48,776) |

*Operating activities*. Net cash used in operating activities was $42.6 million for the nine months ended September 30, 2022, primarily resulting from our net loss of $55.5 million, the change in the fair value of our derivative liability of $8.6 million more than offset by $18.0 million of other non-cash items and net favorable changes in our operating assets and liabilities of $3.5 million,. Our net loss was primarily attributed to research and development activities, selling and marketing expenses, and our general and administrative expenses, which significantly offset any contributions from our revenues to date. Our net non-cash charges during the nine months ended September 30, 2022 consisted primarily of $12.7 million of stock-based compensation expense, $3.6 million in non-cash interest expense and $1.6 million in depreciation and amortization expense and the change in fair value of the derivative liability of $8.6 million. Net cash generated by favorable changes in our operating assets and liabilities during the nine months ended September 30, 2022 consisted primarily of net decreases in accounts receivable, prepaid expenses and other current assets of $2.8 million.

Net cash used in operating activities was $50.4 million for the nine months ended September 30, 2021, primarily resulting from our net loss of $2.7 million and the gain on the change in the fair value of our derivative liability of $62.2 million and partially offset by $16.4 million of other non-cash items and changes in our operating assets and liabilities of $1.9 million. Our net loss was primarily attributed to research and development activities, selling and marketing expenses, and our general and administrative expenses, which significantly offset any contributions from our revenues to

date. Our net non-cash charges during the nine months ended September 30, 2021 consisted primarily of $11.1 million of stock-based compensation expense, $1.9 million in depreciation and amortization expense and non-cash interest expense of $3.4 million and the gain in fair value of the derivative liability of $62.2 million. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2021 consisted primarily of increases in accrued expenses, and accounts receivable as we continue to commercialize DEXTENZA.

*Investing activities*. Net cash used in investing activities for the nine months ended September 30, 2022 and 2021 totaled $1.6 million and $0.6 million, respectively. For both periods, the investing activities were purchases in equipment.

*Financing activities*. Net cash provided by financing activities was $1.0 million for the nine months ended September 30, 2022 and $2.2 million for the nine months ended September 30, 2021. Net cash provided by financing activities for the nine months ended September 30, 2022 of $1.0 million consisted of $0.5 million from the exercise of stock options and $0.5 million in proceeds from the issuance of common stock pursuant to the employee stock purchase plan.

Net cash provided by financing activities for the nine months ended September 30, 2021 of $2.2 million consisted primarily of $2.4 million in proceeds from the exercise of stock options, $3.7 million (net) in borrowings under our Credit Facility and $0.5 million in proceeds from the issuance of common stock pursuant to the employee stock purchase plan partially offset by payments on notes payable of $4.2 million.

***Funding Requirements***

We expect to continue to incur losses in connection with our ongoing activities, particularly as we advance the clinical trials of our product candidates in development and increase our sales and marketing resources to support the ongoing commercialization of DEXTENZA and the potential launch of our product candidates, subject to receiving FDA approval.

We anticipate we will incur substantial expenses if and as we:

- continue to commercialize DEXTENZA in the United States, including for DEXTENZA in the office setting for the treatment of ocular itching associated with allergic conjunctivitis;
- continue to develop and expand our sales, marketing and distribution capabilities for DEXTENZA and any of our products or product candidates we intend to commercialize;
- continue ongoing clinical trials for our product candidates OTX-TKI (in both Australia and the United States) for the treatment of wet AMD and OTX-TIC for the treatment of open-angle glaucoma or ocular hypertension, and our ongoing clinical trial to evaluate DEXTENZA in pediatric subjects following cataract surgery in accordance with the FDA's post-approval requirement;
- determine to initiate new clinical trials to evaluate OTX-TKI for the treatment of wet AMD, diabetic retinopathy and other retinal diseases, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, and OTX-CSI for the chronic treatment of dry eye disease, conduct planned clinical trials to evaluate OTX-TKI for the treatment of diabetic retinopathy and OTX-TKI for the treatment of wet AMD, conduct a collaborative trial in connection with our efforts to develop an appropriate placebo comparator that may be used in both OTX-DED and OTX-CSI programs, and conduct development activities regarding our programs;
- conduct research and development activities on, and seek regulatory approvals for, DEXTENZA and OTX-TIC in specified Asian markets pursuant to our license agreement and collaboration with AffaMed;
- advance our preclinical development programs, including our program to develop a gene therapy product candidate for the treatment of inherited and acquired ocular diseases and our program to develop a product candidate for the treatment of dry AMD through complement inhibition;

- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- scale up our manufacturing processes and capabilities to support sales of commercial products, clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval, and expand our facilities to accommodate this scale up and any corresponding growth in personnel;
- renovate our existing facilities including research and development laboratories, manufacturing space and office space;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial, administrative and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- make investments to improve our cybersecurity defenses and establish and maintain cybersecurity insurance; and
- continue to operate as a public company.

Based on our current plans and forecasted expenses, which includes estimates related to anticipated cash inflows from DEXTENZA product sales and cash outflows from operating expenses, we believe that our existing cash and cash equivalents, as of September 30, 2022, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- the level of product sales from DEXTENZA and any additional products for which we obtain marketing approval in the future and the level of third-party reimbursement of such products;
- the costs of sales, marketing, distribution and other commercialization efforts with respect to DEXTENZA and any additional products for which we obtain marketing approval in the future, including cost increases due to inflation;
- the progress, costs and outcome of our ongoing and planned clinical trials of and ongoing clinical development activities for our product candidates, in particular OTX-TKI for the treatment of wet AMD, diabetic retinopathy and other retinal diseases and OTX-TIC for the treatment of open-angle glaucoma or ocular hypertension;
- the scope, progress, costs and outcome of preclinical development and clinical trials of any other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities;
- the costs of scaling up our manufacturing processes and capabilities to support sales of commercial products, clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval and of expanding our facilities to accommodate this scale up and any corresponding growth in personnel;

- the extent of our debt service obligations and our ability, if desired, to refinance any of our existing debt on terms that are more favorable to us;
- the amounts we are entitled to receive, if any, as reimbursements for clinical trial expenditures, development, regulatory, and sales milestone payments, and royalty payments under our license agreement with AffaMed;
- the extent to which we choose to establish additional collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and outcomes of legal actions and proceedings;
- 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; and
- the extent to which we acquire or invest in other businesses, products and technologies.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. We do not have any committed external source of funds, development, regulatory and sales milestone payments, or royalty payments although our license agreement with AffaMed provides for AffaMed's reimbursement of certain clinical expenses incurred by us in connection with our collaboration and for our potential receipt of development and sales milestone payments as well as royalty payments. To the extent that we raise additional capital through the sale of equity or convertible debt securities, each security holder's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect each security holder's rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. The covenants under our existing Credit Agreement and the pledge of our assets as collateral limit our ability to obtain additional debt financing. If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements, royalty agreements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. In addition, the COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could adversely impact our ability to raise additional funds through equity or debt financings. 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

**Contractual Obligations and Commitments**

We enter into contracts in the normal course of business to assist in the performance of our research and development activities and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts which are not considered contractual obligations and commitments.

During the three and nine months ended September 30, 2022, there were no significant changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2021.

On October 18, 2022, the Company exercised its option to extend the existing operating lease for its manufacturing space located at 36 Crosby Drive in Bedford, Massachusetts (19,786 square feet), which would otherwise have expired on July 31, 2023, by an additional five-year term, resulting in a new expiration date of July 31, 2028. Because rent has not yet been determined, the Company cannot make a reliable estimate of the financial effect of this event at this point. Refer to Note 16 – Subsequent Events to the current period's condensed consolidated financial statements.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission, such relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

**Recently Issued Accounting Pronouncements**

Information regarding new accounting pronouncements is included in Note 2 – *Summary of Significant Accounting Policies* to the current period's condensed consolidated financial statements.

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

We are exposed to market risk related to changes in interest rates. As of September 30, 2022, we had cash and cash equivalents of $121.0 million, which consisted of money market funds. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We do not enter into financial instruments for trading or speculative purposes.

We account for the conversion option embedded in our 2026 Convertible Notes as a separate financial instrument, measured at fair value, using a binomial lattice model, which we refer to as the Derivative Liability. As of September 30, 2022, the Derivative Liability was valued at $11.6 million. As of September 30, 2022, a 10% increase or decrease of the main inputs to the valuation model would not have a material effect on the fair value of the Derivative Liability. Changes of the fair value of the Derivative Liability have no impact on anticipated cash outflows.

As of September 30, 2022, we had a variable interest rate-based note payable with a principal amount of $25.0 million. Expected cash outflows from this financial instrument fluctuate based on changes in the U.S. dollar-denominated LIBOR index which is, among other factors, affected by the general level of U.S. and international central bank interest rates. As of September 30, 2022, an immediate 100 basis point increase or decrease in the U.S. dollar-denominated LIBOR index would not have a material effect on the anticipated cash outflows from this instrument.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management, including our Chief Executive Officer and Chief Financial Officer, recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and

procedures as of September 30, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not presently a party to any material legal proceedings, nor to the knowledge of management are any material legal proceedings threatened against us.

### Item 1A. Risk Factors.

We are subject to a number of risks that could materially and adversely affect our business, financial condition, and results of operations and future growth prospects, including those identified under the heading “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission on February 28, 2022.

### Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the following Exhibit Index.

## EXHIBIT INDEX

| Exhibit Number | Description of Exhibit | Incorporated by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Form | File Number | Date of Filing | Exhibit Number | |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 31.2 | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.1 | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.2 | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 101.INS | Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document) | | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | | | X |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Database | | | | | X |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | | | | | X |
| 104 | The cover page from this Quarterly Report on Form 10-Q, formatted in Inline XBRL and contained in Exhibit 101 | | | | | X |

**SIGNATURES**

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

**OCULAR THERAPEUTIX, INC.**

Date: November 7, 2022

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer
(Principal Financial and Accounting Officer)

**Exhibit 31.1**

**CERTIFICATIONS**

I, Antony Mattessich, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2022

By: /s/ Antony Mattessich
Antony Mattessich
President and Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATIONS**

I, Donald Notman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2022

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer
(Principal Financial and Accounting Officer)

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Ocular Therapeutix, Inc. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Antony Mattessich, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: November 7, 2022

By: /s/ Antony Mattessich
Antony Mattessich
President and Chief Executive Officer
(Principal Executive Officer)

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Ocular Therapeutix, Inc. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Donald Notman, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: November 7, 2022

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer
(Principal Financial and Accounting Officer)