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

# FORM 10-Q

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

**For the quarterly period ended September 30, 2024**

**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 001-35366**

# FORTRESS BIOTECH, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **20-5157386** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**1111 Kane Concourse Suite 301**
**Bay Harbor Islands, FL 33154**
(Address including zip code of principal executive offices)

**(781) 652-4500**
(Registrant's telephone number, including area code)

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

| Title of Class | Trading Symbol(s) | Exchange Name |
|---|---|---|
| Common Stock | FBIO | Nasdaq Capital Market |
| 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock | FBIOP | Nasdaq Capital Market |

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

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

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

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

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

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

| Class of Stock | Outstanding Shares as of November 11, 2024 |
|---|---|
| Common Stock, $0.001 par value | 27,604,934 |
| 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value | 3,427,138 |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Quarterly Report on Form 10-Q**

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## SUMMARY OF RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Item 1A, and the other reports and documents that we have filed with the Securities and Exchange Commission ("SEC"). As used below and throughout this filing (including in the risk factors described in Item 1A), the words "we", "us" and "our" may refer to Fortress Biotech, Inc. individually, to one or more of its subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.

**Risks Inherent in Drug Development**

- Many of our product candidates are in early development stages and are subject to time and cost intensive regulation and clinical testing, which may result in the identification of safety or efficacy concerns. As a result, our product candidates may never be successfully developed or commercialized.
- Our competitors may develop treatments for our products' target indications, which could limit our product candidates' commercial opportunity and profitability.

**Risks Pertaining to the Need for and Impact of Existing and Additional Financing Activities**

- We have a history of operating losses and expect such losses to continue in the future.
- We have funded our operations in part through the assumption of debt, and the applicable lending agreements may restrict our operations. Further, the occurrence of any default event under an applicable loan document could adversely affect our business.
- Our research and development ("R&D") programs will require additional capital, which we may be unable to raise as needed and which may impede our R&D programs, commercialization efforts, or planned acquisitions.
- Our board of directors has paused payments of dividends on our preferred stock, and there can be no assurance that monthly dividend payments will be resumed in a timely manner, or at all.
- If we raise additional capital by issuing equity, equity-linked securities or securities convertible into or exercisable for equity securities, our existing stockholders will be diluted.

**Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation ("Journey")**

- Our operating income derives primarily from the sale of our partner company Journey's dermatology products, particularly Qbrexza, Accutane, Amzeeq and Zilxi. Any issues relating to the manufacture, sale, utilization, or reimbursement of Journey's products (including products liability claims) could significantly impact our operating results.
- A significant portion of Journey's sales derive from products that are without patent protection and/or are or may become subject to third party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse effect on our operating income. Three of Journey's marketed products, Qbrexza, Amzeeq and Zilxi, as well as Emrosi, a modified release oral minocycline for the treatment of rosacea licensed from Dr. Reddy's Laboratories, for which we recently obtained U.S. Food and Drug Administration (the "FDA") approval, currently have patent protection. Four of Journey's marketed products, Accutane, Targadox, Luxamend and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. With respect to Journey products that are covered by valid claims of issued patents, such patents may be subject to invalidation, which would harm our operating income.
- Continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government payors. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of current and newly approved therapeutics.

**Risks Pertaining to our Business Strategy, Structure and Organization**

- We have entered, and will likely in the future enter, into certain collaborations or divestitures which may cause a reduction in our business' size and scope, market share and opportunities in certain markets, or our ability to compete in certain markets and therapeutic categories.

- We and our subsidiaries and partner companies have also entered into, and intend in the future to enter into, arrangements under which we and/or they have agreed to contingent dispositions of such companies and/or their assets. The failure to consummate any such transaction may impair the value of such companies and/or assets, and we may not be able to identify or execute alternative arrangements on favorable terms, if at all. The consummation of any such arrangements with respect to certain product candidates may also result in our eligibility to receive a lower portion of sales (if any) of resulting approved products than if we had developed and commercialized such products ourselves.
- Our growth and success depend on our acquiring or in-licensing products or product candidates and integrating such products into our businesses.
- We act, and are likely to continue acting, as guarantor and/or indemnitor of certain obligations of our subsidiaries, partner companies and partners, which could require us to pay substantial amounts based on the actions or omissions of said entities.

**Risks Pertaining to Reliance on Third Parties**

- We rely heavily on third parties for several aspects of our operations, including manufacturing and developing product candidates, conducting clinical trials, and producing commercial product supply. Such reliance on third parties reduces our ability to control every aspect of the drug development process and may hinder our ability to develop and commercialize our products in a cost-effective and timely manner.

**Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof**

- If we are unable to obtain and maintain patent protection for our technologies and products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies and products similar or identical to ours, and our ability to successfully commercialize our technologies and products may be impaired.
- We or our licensors may be subject to costly and time-consuming litigation for infringement of third-party intellectual property rights or to enforce our or our licensors' patents.
- Any dispute with our licensors may affect our ability to develop or commercialize our product candidates.

**Risks Pertaining to Generic Competition and Paragraph IV Litigation**

- Generic drug companies may submit applications seeking approval to market generic versions of our products.
- In connection with these applications, generic drug companies may seek to challenge the validity and enforceability of our patents through litigation and/or with the United States Patent and Trademark Office ("PTO"). Such challenges may subject us to costly and time-consuming litigation and/or PTO proceedings.
- As a result of the loss of any patent protection from such litigation or PTO proceedings, or the "at-risk" launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of product sales in a short period of time, which could adversely affect our business, financial condition, operating results and prospects.

**Risks Pertaining to the Commercialization of Product Candidates**

- If our product candidates, if approved, are not broadly accepted by the healthcare community, the revenues from any such products are likely to be limited.
- We may not obtain the desired product labels or intended uses for product promotion, or favorable scheduling classifications desirable to successfully promote our products.
- Even if a product candidate is approved, it may be subject to various post-marketing requirements, including studies or clinical trials, the results of which could cause such products to later be withdrawn from the market.
- Any successful products liability claim related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of such products.

**Risks Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries**

- We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations.

**General and Other Risks**

- We have previously failed to satisfy certain continued listing rules of The Nasdaq Stock Market LLC ("Nasdaq"), and if we again are unable to meet the continued listing requirements, our Common Stock and Preferred Stock may be subject to delisting from The Nasdaq Capital Market if we are unable to regain compliance with such rules. The delisting of our Securities from the Nasdaq may decrease the market liquidity and market price of our Common Stock and Preferred Stock.

## PART I. FINANCIAL INFORMATION

### Item 1. Unaudited Condensed Consolidated Financial Statements

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Balance Sheets**
($ in thousands except for share and per share amounts)

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 58,853 | $ 80,927 |
| Accounts receivable, net | 10,671 | 15,222 |
| Inventory | 11,788 | 10,206 |
| Other receivables - related party | 174 | 167 |
| Prepaid expenses and other current assets | 2,583 | 10,500 |
| Assets held for sale | 2,209 | — |
| Total current assets | 86,278 | 117,022 |
| Property, plant and equipment, net | 3,403 | 6,505 |
| Operating lease right-of-use asset, net | 14,152 | 16,990 |
| Restricted cash | 2,063 | 2,438 |
| Intangible assets, net | 17,844 | 20,287 |
| Other assets | 3,345 | 4,284 |
| **Total assets** | **$ 127,085** | **$ 167,526** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | $ 64,499 | $ 73,562 |
| Income taxes payable | 850 | 843 |
| Common stock warrant liabilities | 154 | 886 |
| Operating lease liabilities, short-term | 2,514 | 2,523 |
| Partner company convertible preferred shares, short-term, net | — | 3,931 |
| Partner company installment payments - licenses, short-term | 1,250 | 3,000 |
| Other current liabilities | 1,038 | 163 |
| Total current liabilities | 70,305 | 84,908 |
| Notes payable, long-term, net | 52,473 | 60,856 |
| Operating lease liabilities, long-term | 15,292 | 18,282 |
| Other long-term liabilities | 1,753 | 1,893 |
| **Total liabilities** | **139,823** | **165,939** |
| **Commitments and contingencies (Note 14)** | | |
| **Stockholders' equity (deficit)** | | |
| Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively, liquidation value of $25.00 per share | 3 | 3 |
| Common stock, $0.001 par value, 200,000,000 shares authorized, 27,584,600 and 15,093,053 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 28 | 15 |
| Additional paid-in-capital | 755,229 | 717,396 |
| Accumulated deficit | (734,102) | (694,870) |
| Total stockholders' equity attributed to the Company | 21,158 | 22,544 |
| Non-controlling interests | (33,896) | (20,957) |
| Total stockholders' equity (deficit) | (12,738) | 1,587 |
| **Total liabilities and stockholders' equity (deficit)** | **$ 127,085** | **$ 167,526** |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statements of Operations**
($ in thousands except for share and per share amounts)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| **Revenue** | | | | |
| Product revenue, net | $ 14,629 | $ 15,279 | $ 42,514 | $ 44,405 |
| Collaboration revenue | — | 182 | — | 546 |
| Revenue - related party | — | 31 | 41 | 97 |
| Other revenue | — | 19,260 | — | 19,519 |
| Net revenue | 14,629 | 34,752 | 42,555 | 64,567 |
| | | | | |
| **Operating expenses** | | | | |
| Cost of goods sold - product revenue | 5,285 | 6,429 | 18,642 | 20,645 |
| Research and development | 9,446 | 20,288 | 46,941 | 87,702 |
| Research and development - licenses acquired | — | 60 | — | 4,293 |
| Selling, general and administrative | 21,993 | 21,733 | 60,867 | 71,512 |
| Asset impairment | — | — | 2,649 | 3,143 |
| Total operating expenses | 36,724 | 48,510 | 129,099 | 187,295 |
| Loss from operations | (22,095) | (13,758) | (86,544) | (122,728) |
| | | | | |
| Other income (expense) | | | | |
| Interest income | 589 | 547 | 2,157 | 2,296 |
| Interest expense and financing fee | (6,209) | (2,534) | (10,933) | (13,255) |
| Gain (loss) on common stock warrant liabilities | 19 | 4,542 | (578) | 10,708 |
| Other income (expense) | 1,071 | 620 | 1,334 | (2,049) |
| Total other income (expense) | (4,530) | 3,175 | (8,020) | (2,300) |
| Loss before income tax expense | (26,625) | (10,583) | (94,564) | (125,028) |
| | | | | |
| Income tax expense (refund) | 69 | 141 | (24) | 142 |
| **Net loss** | **(26,694)** | **(10,724)** | **(94,540)** | **(125,170)** |
| | | | | |
| Net loss attributable to non-controlling interests | 13,827 | 5,679 | 55,308 | 73,812 |
| **Net loss attributable to Fortress** | **$ (12,867)** | **$ (5,045)** | **$ (39,232)** | **$ (51,358)** |
| | | | | |
| Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends | (2,173) | (2,008) | (7,006) | (6,024) |
| **Net loss attributable to common stockholders** | **$ (15,040)** | **$ (7,053)** | **$ (46,238)** | **$ (57,382)** |
| | | | | |
| Net loss per common share attributable to common stockholders - basic and diluted | $ (0.76) | $ (0.94) | $ (2.43) | $ (7.94) |
| | | | | |
| Weighted average common shares outstanding - basic and diluted | 19,697,290 | 7,498,653 | 19,041,590 | 7,231,004 |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit)**
($ in thousands except for share amounts)

**For the Three Months Ended September 30, 2024**

| | Series A Perpetual Preferred Stock | | Common Stock | | Common Shares Issuable | Paid-In Capital | Accumulated Deficit | Non-Controlling Interests | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | | |
| **Balance as of June 30, 2024** | **3,427,138** | **$ 3** | **22,587,038** | **$ 23** | **$ —** | **$ 739,086** | **$ (721,235)** | **$ (32,475)** | **$ (14,598)** |
| Stock-based compensation expense | — | — | — | — | — | 6,573 | — | — | 6,573 |
| Issuance of common stock related to equity plans | — | — | 51,435 | — | — | — | — | — | — |
| Issuance of common stock for equity offering, net | | | 4,702,753 | 5 | | 7,355 | | | 7,360 |
| Warrants issued in conjunction with debt | — | — | — | — | — | 1,314 | — | — | 1,314 |
| Issuance of common stock for at-the-market offering, net | — | — | 243,374 | — | — | 568 | — | — | 568 |
| Partner companies' offerings, net | — | — | — | — | — | 10,850 | — | — | 10,850 |
| Partner company's at-the-market offering, net | — | — | — | — | — | 1,878 | — | — | 1,878 |
| Issuance of common stock under partner company's ESPP | — | — | — | — | — | 124 | — | — | 124 |
| Partner company's dividends declared and paid | — | — | — | — | — | (176) | — | — | (176) |
| Partner companies' proceeds from options | — | — | — | — | — | 63 | — | — | 63 |
| Non-controlling interest in partner companies | — | — | — | — | — | (12,406) | — | 12,406 | — |
| Net loss attributable to non-controlling interest | — | — | — | — | — | — | — | (13,827) | (13,827) |
| Net loss attributable to common stockholders | — | — | — | — | — | — | (12,867) | — | (12,867) |
| **Balance as of September 30, 2024** | **3,427,138** | **$ 3** | **27,584,600** | **$ 28** | **$ —** | **$ 755,229** | **$ (734,102)** | **$ (33,896)** | **$ (12,738)** |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit)**
($ in thousands except for share amounts)

**For the Three Months Ended September 30, 2023**

| | Series A Perpetual Preferred Stock | | Common Stock | | Common Shares Issuable | Paid-In Capital | Accumulated Deficit | Non-Controlling Interests | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | | |
| **Balance as of June 30, 2023** | **3,427,138** | **$ 3** | **8,777,157** | **$ 9** | **$ 23** | **$ 699,020** | **$ (680,546)** | **$ (34,452)** | **$ (15,943)** |
| Stock-based compensation expense | — | — | — | — | — | 4,377 | — | — | 4,377 |
| Issuance of common stock related to equity plans | — | — | 28,112 | — | — | — | — | — | — |
| Issuance of common stock for at-the-market offering, net | — | — | 117,578 | — | — | 837 | — | — | 837 |
| Common shares issued for dividend on partner company's convertible preferred shares | — | — | 14,740 | — | (23) | 91 | — | — | 68 |
| Preferred A dividends declared and paid | — | — | — | — | — | (2,008) | — | — | (2,008) |
| Partner company's offering, net | — | — | — | — | — | 9,261 | — | — | 9,261 |
| Partner company's at-the-market offering, net | | | | | | 160 | | | 160 |
| Issuance of common stock under partner company's ESPP | — | — | — | — | — | 90 | — | — | 90 |
| Partner company's dividends declared and paid | — | — | — | — | — | (185) | — | — | (185) |
| Partner company's exercise of options for cash | — | — | — | — | — | 21 | — | — | 21 |
| Dissolution of subsidiary non-controlling interests | — | — | — | — | | — | — | — 802 | — 802 |
| Non-controlling interest in partner companies | — | — | — | — | — | (9,412) | — | 9,412 | — |
| Net loss attributable to non-controlling interest | — | — | — | — | — | — | — | (5,679) | (5,679) |
| Net loss attributable to common stockholders | — | — | — | — | — | — | (5,045) | — | (5,045) |
| **Balance as of September 30, 2023** | **3,427,138** | **$ 3** | **8,937,587** | **$ 9** | **$ —** | **$ 702,253** | **$ (685,591)** | **$ (29,917)** | **$ (13,243)** |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit)**
($ in thousands except for share amounts)

**For the Nine Months Ended September 30, 2024**

| | Series A Preferred Stock | | Common Stock | | Paid-In Capital | Accumulated Deficit | Total Non-Controlling Interests | Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| **Balance as of December 31, 2023** | **3,427,138** | **$ 3** | **15,093,053** | **$ 15** | **$ 717,396** | **$ (694,870)** | **$ (20,957)** | **$ 1,587** |
| Stock-based compensation expense | — | — | — | — | 16,429 | — | — | 16,429 |
| Issuance of common stock related to equity plans | — | — | 547,196 | — | — | — | — | — |
| Issuance of common stock under ESPP | — | — | 29,844 | — | 51 | — | — | 51 |
| Issuance of common stock for equity offerings, net | — | — | 8,006,058 | 8 | 17,470 | — | — | 17,478 |
| Warrants issued in conjunction with debt | — | — | — | — | 1,313 | — | — | 1,313 |
| Issuance of common stock for at-the-market offering, net | — | — | 1,797,857 | 2 | 3,392 | — | — | 3,394 |
| Common shares issued for dividend on partner company's convertible preferred shares | — | — | 64,747 | — | 114 | — | — | 114 |
| Common shares issued for exchange of partner company's convertible preferred shares | — | — | 2,028,345 | 3 | 3,406 | — | — | 3,409 |
| Warrants issued in conjunction with exchange of partner company's convertible preferred shares | | | | | 341 | | | 341 |
| Preferred A dividends declared and paid | — | — | — | — | (4,016) | — | — | (4,016) |
| Partner companies' offerings, net | — | — | — | — | 28,852 | — | — | 28,852 |
| Partner companies' at-the-market offering, net | — | — | — | — | 3,657 | — | — | 3,657 |
| Issuance of common stock under partner company's ESPP | — | — | — | — | 257 | — | — | 257 |
| Partner company's dividends declared and paid | — | — | — | — | (528) | — | — | (528) |
| Exercise of warrants for cash | — | — | 17,500 | — | 30 | — | — | 30 |
| Exercise of partner company options and warrants for cash, net | — | — | — | — | 9,434 | — | — | 9,434 |
| Non-controlling interest in partner companies | — | — | — | — | (42,369) | — | 42,369 | — |
| Net loss attributable to non-controlling interest | — | — | — | — | — | — | (55,308) | (55,308) |
| Net loss attributable to common stockholders | — | — | — | — | — | (39,232) | — | (39,232) |
| **Balance as of September 30, 2024** | **3,427,138** | **$ 3** | **27,584,600** | **$ 28** | **$ 755,229** | **$ (734,102)** | **$ (33,896)** | **$ (12,738)** |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statement of Changes in Stockholders' Equity**
($ in thousands except for share amounts)

**For the Nine Months Ended September 30, 2023**

| | Series A Preferred Stock | | Common Stock | | Paid-In Capital | Additional Accumulated Deficit | Non-Controlling Interests | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| **Balance as of December 31, 2022** | **3,427,138** | **$ 3** | **7,366,283** | **$ 7** | **$ 675,944** | **$ (634,233)** | **$ 8,304** | **$ 50,025** |
| Stock-based compensation expense | — | — | — | — | 13,325 | — | — | 13,325 |
| Issuance of common stock related to equity plans | — | — | 211,969 | — | — | — | — | — |
| Issuance of common stock for public offering, net | — | — | 1,109,525 | 1 | 13,154 | — | — | 13,155 |
| Issuance of common stock for at-the-market offering, net | — | — | 224,003 | 1 | 2,004 | — | — | 2,005 |
| Common shares issued for dividend on partner company's convertible preferred shares | — | — | 25,807 | — | 199 | — | — | 199 |
| Preferred A dividends declared and paid | — | — | — | — | (6,024) | — | — | (6,024) |
| Partner company's offering, net | — | — | — | — | 31,238 | — | — | 31,238 |
| Partner companies' at-the-market offering, net | — | — | — | — | 160 | — | — | 160 |
| Partner company's exercise of options for cash | — | — | — | — | 24 | — | — | 24 |
| Issuance of common stock under partner company's ESPP | — | — | — | — | 178 | — | — | 178 |
| Partner company's dividends declared and paid | — | — | — | — | (556) | — | — | (556) |
| Issuance of partner company's common shares for research and development expenses | — | — | — | — | 1,233 | — | — | 1,233 |
| Warrants | — | — | — | — | 272 | — | — | 272 |
| Deconsolidation of Aevitas non-controlling interest | — | — | — | — | — | — | 6,693 | 6,693 |
| Non-controlling interest in partner companies | — | — | — | — | (28,898) | — | 28,898 | — |
| Net loss attributable to non-controlling interest | — | — | — | — | — | — | (73,812) | (73,812) |
| Net loss attributable to common stockholders | — | — | — | — | — | (51,358) | — | (51,358) |
| **Balance as of September 30, 2023** | **3,427,138** | **$ 3** | **8,937,587** | **$ 9** | **$ 702,253** | **$ (685,591)** | **$ (29,917)** | **$ (13,243)** |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statements of Cash Flows**
($ in thousands)

| | Nine Months Ended September 30, 2024 | 2023 |
|---|---|---|
| **Cash Flows from Operating Activities:** | | |
| Net loss | $ (94,540) | $ (125,170) |
| **Reconciliation of net loss to net cash used in operating activities:** | | |
| Depreciation expense | 896 | 1,853 |
| Loss on disposal of property and equipment | 29 | (1,351) |
| Bad debt expense | 823 | 492 |
| Amortization of debt discount | 1,754 | 2,524 |
| Accretion of partner company convertible preferred shares | (737) | 687 |
| Non-cash interest | — | 353 |
| Loss on extinguishment of debt | 2,457 | 2,796 |
| Amortization of acquired intangible assets | 2,443 | 2,952 |
| Reduction in the carrying amount of operating lease right-of-use assets | 2,366 | 1,561 |
| Stock-based compensation expense | 16,429 | 13,325 |
| Issuance of partner company's common shares for research and development expenses | — | 1,233 |
| Common shares issued for dividend on partner company's convertible preferred shares | 114 | 199 |
| Change in fair value of partner companies' warrant liabilities | 427 | (10,708) |
| Research and development - licenses acquired, expense | — | 3,060 |
| Loss from deconsolidation/dissolution of subsidiaries | — | 4,127 |
| Asset impairment loss | 2,649 | 3,143 |
| **Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:** | | |
| Accounts receivable | 3,728 | 19,727 |
| Inventory | (1,582) | 3,135 |
| Other receivables - related party | (7) | (27) |
| Prepaid expenses and other current assets | 3,903 | 3,217 |
| Other assets | 939 | (1,107) |
| Accounts payable and accrued expenses | (7,118) | (17,018) |
| Income taxes payable | 7 | 84 |
| Lease liabilities | (2,999) | (1,739) |
| Other long-term liabilities | 735 | (638) |
| Net cash used in operating activities | (67,284) | (93,290) |
| | | |
| **Cash Flows from Investing Activities:** | | |
| Purchase of research and development licenses | — | (3,000) |
| Purchase of property and equipment | — | (35) |
| Proceeds from sale of property and equipment | — | 6,000 |
| Other | — | (5) |
| Acquired intangible assets | — | (5,000) |
| Net cash used in investing activities | — | (2,040) |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statements of Cash Flows**
($ in thousands)

| | Nine Months Ended September 30, 2024 | 2023 |
|---|---|---|
| **Cash Flows from Financing Activities:** | | |
| Payment of Series A perpetual preferred stock dividends | $ (4,016) | $ (6,024) |
| Proceeds from issuance of common stock for equity offerings, net | 17,478 | 13,248 |
| Proceeds from issuance of common stock for at-the-market offering, net | 3,394 | 2,056 |
| Proceeds from issuance of common stock under ESPP | 51 | — |
| Exercise of warrants for cash | 30 | — |
| Proceeds from partner companies' ESPP | 257 | 178 |
| Partner company's dividends declared and paid | (528) | (556) |
| Proceeds from partner companies' sale of stock, options and warrants, net | 37,128 | 33,805 |
| Proceeds from partner companies' at-the-market offering, net | 3,657 | 160 |
| Proceeds from exercise of partner companies' equity grants | — | 24 |
| Repayment of Oaktree Note and debt issuance costs | (51,000) | — |
| Repayment of partner company installment payments - licenses | (625) | (1,000) |
| Proceeds from partner company convertible preferred shares | — | 854 |
| Stock and warrants issued for exchange of partner company preferred shares | 341 | — |
| Payment of debt issuance costs associated with partner company convertible preferred shares | — | (210) |
| Proceeds from long-term debt, net | 33,718 | — |
| Proceeds from partner company's long-term debt, net | 4,950 | (91) |
| Repayment of partner companies' long-term debt | — | (50,375) |
| Proceeds from partner company's line of credit | — | 28,000 |
| Repayment of partner company's line of credit | — | (30,948) |
| Net cash (used in) provided by financing activities | 44,835 | (10,879) |
| Net increase (decrease) in cash and cash equivalents and restricted cash | (22,449) | (106,209) |
| Cash and cash equivalents and restricted cash at beginning of period | 83,365 | 180,954 |
| **Cash and cash equivalents and restricted cash at end of period** | $ 60,916 | $ 74,745 |
| | | |
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for interest | $ 5,401 | $ 6,590 |
| Cash paid (refunded) for income taxes | $ 115 | $ (17) |
| | | |
| **Supplemental disclosure of non-cash financing and investing activities:** | | |
| Exchange of partner company convertible preferred shares for common shares | $ 3,408 | $ — |
| Fair value of assets received by partner company in repurchase transaction | $ 2,209 | — |
| Fair value of supplies received by partner company expensed to research and development | $ 2,509 | — |
| Partner company accounts receivable write-off related to repurchase transaction | $ (6,967) | — |
| Partner company accounts payable write-off related to repurchase transaction | $ 3,644 | — |
| Partner company's deferred purchase consideration | $ (1,295) | — |
| Unpaid partner company's offering cost | $ — | $ 575 |
| Partner company derivative warrant liability associated with partner company convertible preferred shares | $ — | $ 33 |
| Warrants issued in conjunction with debt | $ 1,313 | $ — |
| Unpaid debt offering cost | $ 140 | $ — |
| Unpaid at-the-market offering cost | $ — | $ 50 |
| Prepaid public offering cost | $ — | $ 94 |
| Unpaid research and development licenses acquired | $ — | $ 60 |

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Organization and Description of Business**

Fortress Biotech, Inc. ("Fortress" or the "Company") is a biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holding and dividend and royalty revenue streams. Fortress works in concert with its extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. The Company has executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center ("COH" or "City of Hope"), Fred Hutchinson Cancer Center, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and finance expertise to help the partners achieve their goals. Partner and subsidiary companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, sales transactions, and public and private financings. To date, four partner companies are publicly-traded, and three subsidiaries have consummated strategic partnerships with industry leaders, including AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl").

Our subsidiaries and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are: Avenue Therapeutics, Inc. (Nasdaq: ATXI, "Avenue"), Baergic Bio, Inc. ("Baergic", a subsidiary of Avenue), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, "Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation (Nasdaq: DERM, "Journey" or "JMC"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang") and Oncogenuity, Inc. ("Oncogenuity").

As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually, to one or more of its subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context. Generally, "subsidiary" refers to a private Fortress subsidiary, "partner company" refers to a public Fortress subsidiary, and "partner" refers to an entity with whom one of the foregoing parties has a significant business relationship, such as an exclusive license or an ongoing product-related payment obligation. The context in which any such term is used throughout this document, however, may dictate a different construal from the foregoing.

*Liquidity and Capital Resources*

Since inception, the Company's operations have been financed primarily through the sale of equity and debt securities, from the sale of subsidiaries/partner companies, and the proceeds from the exercise of warrants. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. Current cash and cash equivalents of $25.6 million for Fortress and private subsidiaries primarily funded by Fortress ("Parent Entity") are considered sufficient to fund the Parent Entity's operations for at least the next 12 months. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, sale of partner companies, grants or other arrangements to develop and prepare regulatory filings and obtain regulatory approvals for the existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the potential products, sales and marketing capabilities. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plans and plans for expansion of its general and administrative infrastructure may be curtailed. Fortress also has the ability, subject to limitations imposed by Rule 144 of the Securities Act of 1933 and other applicable laws and regulations, to raise money from the sale of common stock of the public companies in which it has ownership positions.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies**

**Basis of Presentation and Principles of Consolidation**

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the unaudited condensed consolidated financial statements have read or have access to the audited financial statements for the preceding fiscal year for each of Avenue, Checkpoint, Mustang and Journey. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 28, 2024 (the "2023 Form 10-K"), from which the Company derived the balance sheet data at December 31, 2023, as well as Checkpoint's Form 10-K, filed with the SEC on March 22, 2024, Mustang's Form 10-K, filed with the SEC on March 11, 2024, Avenue's Form 10-K, filed with the SEC on March 18, 2024, and Journey's Form 10-K, filed with the SEC on March 29, 2024.

The Company's unaudited condensed consolidated financial statements include the results of the Company's subsidiaries for which it has voting control but does not own 100% of the outstanding equity of the subsidiaries. For consolidated entities where the Company owns less than 100% of the subsidiary, but retains voting control, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations and presents non-controlling interests as a component of stockholders' equity on its consolidated balance sheets. All intercompany income and/or expense items are eliminated entirely in consolidation prior to the allocation of net gain/loss attributable to non-controlling interest, which is based on ownership interests as calculated quarterly for each subsidiary.

**Use of Estimates**

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period. The Company's significant estimates include, but are not limited to provisions for coupons, chargebacks, wholesaler fees, specialty pharmacy discounts, managed care rebates, product returns, inventory realization, valuation of intangible assets, useful lives assigned to long-lived assets and amortizable intangible assets, fair value of stock options and warrants, stock-based compensation, common stock issued to acquire licenses, accrued expenses and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

**Restricted Cash**

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of September 30, 2024 and December 31, 2023, the Company had $2.1 million and $2.4 million, respectively, of restricted cash representing pledges to secure debt obligations and letters of credit in connection with certain office leases, and an undertaking posted by Cyprium to secure potential damages in an injunctive proceeding.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

The following table provides a reconciliation of cash, cash equivalents, and restricted cash from the unaudited condensed consolidated balance sheets to the unaudited condensed consolidated statements of cash flows as of the dates presented:

| | September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Cash and cash equivalents | $ 58,853 | $ 72,307 |
| Restricted cash | 2,063 | 2,438 |
| Total cash and cash equivalents and restricted cash | $ 60,916 | $ 74,745 |

**Significant Accounting Policies**

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2023 Form 10-K other than the following:

***Assets Held for Sale***

Assets held for sale represent assets that have met the criteria of "held for sale" accounting, as specified by Accounting Standards Codification ("ASC") 360, "Long-lived Assets." As of September 30, 2024, there are $2.2 million of lab and cell processing equipment, furniture and fixtures and computer equipment that are recorded as assets held for sale. The effect of suspending depreciation on the assets held for sale is immaterial to the results of operations. The assets held for sale are part of Mustang's repurchase of assets from uBriGene (Boston) Biosciences, Inc. ("uBriGene") (see Note 3).

**Recently Issued Accounting Pronouncements**

*Accounting Standards Not Yet Adopted*

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires that an entity report segment information in accordance with Topic 280, Segment Reporting. The amendment in the ASU is intended to improve reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments in this update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact of the new standard on its financial statement disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands disclosures in an entity's income tax rate reconciliation table and disclosures regarding cash taxes paid both in the U.S. and foreign jurisdictions. The update will be effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact that this guidance will have on its financial statement disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires new financial statement disclosures in tabular format, in the notes to financial statements, of specified information about certain costs and expenses. The amendments in this update do not change or remove current expense disclosure requirements. The amendments in this update are effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the new standard on its financial statement disclosures.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

**3. Asset Purchase Agreements**

***Mustang***

Agreements with uBriGene

On May 18, 2023, Mustang entered into an Asset Purchase Agreement (the "Original Asset Purchase Agreement") with uBriGene, pursuant to which Mustang agreed to sell its leasehold interest in its cell processing facility located in Worcester, Massachusetts (the "Facility"), and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene (the "Transaction"). Mustang and uBriGene subsequently entered into Amendment No. 1 to the Original Asset Purchase Agreement, dated as of June 29, 2023 ("Amendment No. 1"), and Amendment No. 2 to the Original Asset Purchase Agreement, dated as of July 28, 2023 ("Amendment No. 2," and together with the Original Asset Purchase Agreement and Amendment No. 1, the "Prior Asset Purchase Agreement").

On July 28, 2023, pursuant to the Prior Asset Purchase Agreement, Mustang completed the sale of all of its assets that primarily relate to the manufacturing and production of cell and gene therapies at the Facility (such operations, the "Transferred Operations" and such assets, the "Transferred Assets") to uBriGene for upfront consideration of $6 million cash (the "Base Amount"). The Transferred Assets included all of Mustang's assets, except for Mustang's lease and related leasehold improvements of the Facility and contracts that are primarily used in the Transferred Operations. Mustang recorded a gain of $1.4 million in connection with the sale of the Transferred Assets and recorded approximately $0.3 million of the base consideration as deferred income, that was to be recognized upon the transfer of the lease.

In connection with the Prior Asset Purchase Agreement, Mustang and uBriGene submitted a voluntary joint notice to the U.S. Committee on Foreign Investment in the United States ("CFIUS"). Following CFIUS's review and subsequent investigation of the transactions related to the Prior Asset Purchase Agreement, on May 13, 2024, Mustang, together with uBriGene and CFIUS, executed a National Security Agreement (the "NSA"), pursuant to which Mustang and uBriGene agreed to abandon the transactions related to the Prior Asset Purchase Agreement and the agreements entered into in connection therewith. The NSA obligated uBriGene and Mustang to terminate agreements between the two parties, including the Manufacturing Services Agreement, Quality Services Agreement, and Subcontracting CDMO Agreement. In addition, uBriGene must sell, or otherwise dispose of, the equipment assets purchased within 180 days after the execution of the NSA.

June 2024 Repurchase of Assets

On June 27, 2024 (the "Effective Date"), Mustang entered into an Asset Purchase Agreement (the "Repurchase Agreement") with uBriGene, pursuant to which Mustang agreed, subject to the terms and conditions set forth therein, to repurchase the Transferred Assets, primarily lab equipment and supplies (collectively, the "Repurchased Assets"). Pursuant to the terms of the Repurchase Agreement, Mustang and uBriGene also terminated existing manufacturing and services agreements.

As consideration for the Repurchase Agreement, Mustang has agreed to pay to uBriGene a total purchase price (the "Purchase Price") of $1.4 million, consisting of (i) an upfront payment of $0.1 million due within five (5) business days of the Effective Date and a (ii) subsequent amount of $1.3 million due on the date that is twelve (12) months after the closing date (the "Deferred Amount"). In the event that as of the original (or any extended) date on which the Deferred Amount is payable, Mustang has, as of the date of the public reporting of its then-most recent quarterly audited or unaudited financial statements, net assets below $20 million, then Mustang may, upon written notice to uBriGene, elect to delay its payment obligation of the Deferred Amount by an additional six (6) months, with no limit on the number of such extensions available to Mustang. Notwithstanding the foregoing, if Mustang has not paid the Deferred Amount in full as of the date that is twelve (12) months after closing of the Repurchase Agreement, any amounts that remain outstanding will accrue interest at a rate of 5% per annum beginning on the date that is twelve (12) months after closing and until the Deferred Amount is paid in full. Additionally, in connection with the termination of the agreements described above under the Repurchase Agreement, Mustang agreed to forgive a net receivable from uBriGene of approximately $3.3 million, comprised of outstanding receivables of $6.9 million and payables of $3.6 million, resulting in total purchase consideration in the Repurchase Transactions of approximately $4.7 million. As of September 30, 2024, the $1.3 million Purchase Price was recorded in Accrued Expenses - Other (see Note 10). As of September 30, 2024, the disposal group continues to be held for sale.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

Mustang allocated the total purchase consideration of $4.7 million to the Repurchased Assets on a relative fair value basis. Mustang used a third-party to perform a valuation of the repurchased equipment, which resulted in a fair value less costs to sell of approximately $2.2 million. The remaining purchase consideration of $2.5 million was allocated to the supplies repurchased. The supplies repurchased with no alternative future use were recognized as research and development expense in an amount of $2.2 million. Repurchased supplies with an alternative future use of $0.3 million were also recognized in research and development expense, as Mustang does not have plans to resume operations in the facility, and it intends to dispose of the supplies in a single transaction with the equipment. Mustang concluded that the disposal group, which includes the repurchased equipment assets and associated supplies with an aggregate value of approximately $2.2 million, met the criteria to be classified as held for sale at the date of acquisition.

***Urica***

On July 15, 2024, Urica entered into an asset purchase agreement (the "APA"), royalty agreement (the "Royalty Agreement"), and related agreements (collectively, the "Transaction Documents") with Crystalys Therapeutics, Inc. ("Crystalys"). Crystalys is a Delaware corporation incorporated in 2022 and seeded by life sciences institutional investors. Under the Transaction Documents, Urica sold the rights to its URAT1 inhibitor product candidate in development for the treatment of gout, dotinurad, and related intellectual property, licenses and agreements to Crystalys. In return, Crystalys issued to Urica shares of its common stock equal to 35% of Crystalys' outstanding equity. Urica's equity position cannot be reduced below 15% of Crystalys' fully-diluted equity capitalization until it raises $150 million in equity securities.

The Transaction Documents also grant Urica a securitized three percent (3%) royalty on future net sales of dotinurad to be paid by Crystalys, as well as the right to receive $0.6 million cash reimbursement for certain clinical and development costs incurred by Urica related to dotinurad. Urica has the right to appoint one director to the board of directors of Crystalys, as well as an additional board observer. Crystalys is obliged to use commercially reasonable efforts to develop and commercialize dotinurad.

The APA also gives Urica the right, but not the obligation, to repurchase the sold assets for a repurchase price not to exceed $6.4 million plus accrued interest; the repurchase option expires upon the consummation by Crystalys of a qualified financing of at least $120 million occurring within the earlier to occur of (i) twelve months after receipt by Crystalys of minutes from an anticipated FDA meeting; or (ii) July 15, 2026. Urica recorded a liability for the $0.6 million received, which will be accreted up to the repurchase price over the term of the repurchase option, and will not recognize an asset for its ownership interest received in Crystalys until the expiration of the repurchase option. Accordingly, for the quarter ended September 30, 2024, Urica recorded accretion of $0.3 million of the repurchase option price, booked to interest expense in the condensed consolidated statement of operations.

***Avenue***

InvaGen Pharmaceuticals Inc. ("InvaGen") Share Repurchase

Under the Share Repurchase Agreement between Avenue and InvaGen Pharmaceuticals, Inc. ("InvaGen") under which Avenue repurchased all of InvaGen's shares in Avenue, Avenue agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the net proceeds of future financings, until $4.0 million in the aggregate is paid to InvaGen. In connection with equity financings in the nine months ended September 30, 2024, Avenue made payments totaling $0.7 million to InvaGen.

**4. Inventory**

| *($ in thousands)* | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Raw materials | $ 3,551 | $ 4,640 |
| Work-in-process | — | 884 |
| Finished goods | 8,718 | 4,987 |
| Inventory reserve | (481) | (305) |
| Total inventories | $ 11,788 | $ 10,206 |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

## 5. Property and Equipment

| *($ in thousands)* | Useful Life (Years) | September 30, 2024 | December 31, 2023 |
|---|---|---|---|
| Computer equipment | 3 | $ 595 | $ 595 |
| Furniture and fixtures | 5 | 1,017 | 1,017 |
| Leasehold improvements | 15 | 13,175 | 13,175 |
| Buildings | 40 | 581 | 581 |
| Construction in progress | N/A | — | 29 |
| Total property and equipment | | 15,368 | 15,397 |
| Less: Accumulated depreciation | | (11,965) | (8,892) |
| Property and equipment, net | | $ 3,403 | $ 6,505 |

Fortress' depreciation expense for the three months ended September 30, 2024 and 2023 was approximately $0.1 million and $0.4 million, respectively, and for the nine months ended September 30, 2024 and 2023 was approximately $0.9 million and $1.9 million, respectively. Fortress' depreciation expense is recorded in both research and development expense and general and administrative expense in the condensed consolidated statement of operations.

*Impairment of Long-Lived Assets*

During the nine months ended September 30, 2024, Mustang concluded it had a triggering event requiring assessment of impairment for certain leasehold improvements and the related right of use asset. Mustang assessed the carrying value of the asset group consisting of the leasehold improvements and right-of-use asset in accordance with ASC 360, given the significant changes to Mustang's operations, operating cash and the repurchase of equipment. The assessment of the recoverability of the asset group concluded that there was impairment on the carrying value of the asset group of approximately $2.6 million, which was allocated on a pro rata basis using the relative carrying amounts of the assets. Approximately $2.2 million of the impairment loss was allocated to leasehold improvements, with the remaining $0.4 million allocated to the right-of-use asset.

## 6. Fair Value Measurements

Common Stock Warrant Liabilities

| *($ in thousands)* | Warrants liabilities |
|---|---|
| Balance at December 31, 2023 | $ 886 |
| Change in fair value of common stock warrants - Avenue | (157) |
| Change in fair value of common stock warrants - Checkpoint | — |
| Change in fair value of placement agent warrants - Urica | (24) |
| Exercise of common stock warrants - Avenue | (400) |
| Exchange of common stock warrants - Urica | (151) |
| Balance at September 30, 2024 | $ 154 |

***Checkpoint***

Checkpoint deemed the placement agent warrants it issued in connection with its registered direct offering (the "December 2022 Placement Agent Warrants") to be classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside its control. The December 2022 Placement Agent Warrants were recorded at the time of closing at a fair value determined by using the Black-Scholes model. Checkpoint will revalue the December 2022 Placement Agent Warrants at each reporting period thereafter for as long as they remain outstanding. At September 30, 2024 and December 31, 2023, the liability associated with the December 2022 Placement Agent Warrants was $0.1 million.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

| *Checkpoint Warrants* | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Exercise price | $ 5.41 | $ 5.41 |
| Volatility | 108.0 % | 96.4 % |
| Expected life in years | 3.2 | 4.0 |
| Risk-free rate | 3.6 % | 3.8 % |

***Avenue***

Certain of Avenue's outstanding warrants to purchase shares of its common stock are classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside of its control. The Black-Scholes model was used to value these Avenue warrants, at the time of issuance and when re-measured at each financial reporting date, up to exercise or expiration of the warrants, with any changes in fair value being recognized in change in fair value of warrant liabilities, a component of other income (expense) in the unaudited condensed consolidated statements of operations. At September 30, 2024 and December 31, 2023, the liability associated with the outstanding Avenue warrants was approximately $29,000 and $0.6 million, respectively.

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

| | September 30, 2024 | December 31 2023 |
|---|---|---|
| Stock price | $ 2.49 | $ 12.00 |
| Risk-free interest rate | 3.58 % | 3.84 % |
| Expected dividend yield | — | — |
| Expected term in years | 3.0 | 3.8 |
| Expected volatility | 164 % | 148 % |

***Urica***

Urica's outstanding contingently issuable placement agent warrants were exchanged at the time of the exchange of the Urica 8% Cumulative Convertible Class B Preferred Stock on June 27, 2024 (see Note 9) for 202,834 warrants to purchase Fortress common stock at an exercise price of $1.68. The Fortress common stock warrants have a five-year life, expiring on June 27, 2029. The Company determined the placement agent warrants met the criteria for equity classification.

**7. Intangible Assets, net**

The Company's finite-lived intangible assets consist of intangible assets acquired by Journey. The table below provides a summary of the Journey intangible assets for the periods presented:

| *($ in thousands)* | Estimated Useful Lives (Years) | September 30, 2024 | December 31, 2023 |
|---|---|---|---|
| Intangible assets – product licenses | 3 to 9 | $ 37,925 | $ 37,925 |
| Accumulated amortization | | (16,938) | (14,495) |
| Accumulated Impairment loss | | (3,143) | (3,143) |
| Net intangible assets | | $ 17,844 | $ 20,287 |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

For the three months ended September 30, 2024 and 2023, Journey's amortization expense related to its product licenses was $0.8 million and $0.8 million, respectively. For the nine months ended September 30, 2024 and 2023, Journey's amortization expense related to its product licenses was $2.4 million and $3.0 million, respectively. Journey records amortization expense related to its product licenses as a component of cost of goods sold on the unaudited condensed consolidated statement of operations.

The future amortization of these intangible assets is as follows:

| *($ in thousands)* | Total Amortization |
|---|---|
| Remainder of 2024 | $ 814 |
| December 31, 2025 | 3,257 |
| December 31, 2026 | 2,471 |
| December 31, 2027 | 1,775 |
| December 31, 2028 | 1,595 |
| Thereafter | 3,990 |
| Sub-total | $ 13,902 |
| Asset not yet placed in service | 3,942 |
| Total | $ 17,844 |

**8. License Agreements**

In accordance with ASC 730-10-25-1, Research and Development, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. The licenses purchased by Fortress and its subsidiaries and partner companies require substantial completion of research and development, and regulatory and marketing approval efforts, in order to reach technological feasibility. As such, the purchase price of any licenses acquired is classified as research and development-licenses acquired in the unaudited condensed consolidated statement of operations.

***Journey***

In June 2021, Journey entered a license, collaboration, and assignment agreement (the "DFD-29 Agreement") to obtain global rights for the development and commercialization of Emrosi™ (Minocycline Hydrochloride Extended-Release Capsules, 40mg), also known as DFD-29, for the treatment of rosacea with Dr. Reddy's Laboratories, Ltd ("DRL"); provided, that DRL retained certain rights to the program in select markets including Brazil, Russia, India and China. Pursuant to the terms and conditions of the DFD-29 Agreement, Journey paid $10.0 million. Based on the development and commercialization of Emrosi, additional contingent regulatory and commercial milestone payments totaling up to $140.0 million, which excludes a $15.0 million milestone payment triggered by FDA approval on November 4, 2024, may also become payable by Journey (see Note 19). Journey is required to pay royalties ranging from approximately ten percent to twenty percent on net sales of Emrosi, subject to certain reductions.

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## 9. Debt and Interest

***Debt***

Total debt consists of the following:

| *($ in thousands)* | September 30, 2024 | December 31, 2023 | Interest rate | Maturity |
|---|---|---|---|---|
| 2024 Oaktree Note | $ 35,350 | $ — | 12.9 % | July - 2027 |
| 2020 Oaktree Note | — | 50,000 | 11.0 % | August - 2025 |
| SWK Term Loan | 20,000 | 15,000 | 14.9 % | December - 2027 |
| Less: Discount on notes payable | (2,877) | (4,144) | | |
| Total notes payable | $ 52,473 | $ 60,856 | | |

*2024 Oaktree Note*

On July 25, 2024, Fortress entered into the $50.0 million senior secured credit agreement (the "New Oaktree Agreement") with a maturity date of July 25, 2027 with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). The Company borrowed $35.0 million under the New Oaktree Agreement on the Closing Date (the "2024 Oaktree Note") and is eligible to draw up to an additional $15.0 million at the lenders' discretion to support future business development activities. The 2024 Oaktree Note replaces the 2020 Oaktree Note (as defined below) in which the remaining $50.0 million balance was repaid in full.

Under the terms of the New Oaktree Agreement, the loans have a 30-month interest-only period with a maturity date of July 25, 2027, and bear interest at an annual rate equal to the 3-month Secured Overnight Financing Rate (SOFR) plus 7.625% (subject to a 2.50% SOFR floor and a 5.75% SOFR cap). For the quarter ended September 30, 2024, the interest rate applicable to the 2024 Oaktree Note was 12.91%. The Company is required to make quarterly interest-only payments until the maturity date, except fifty percent of the then-outstanding principal balance of the loans is due on March 31, 2027, with the remaining principal amount due on the maturity date.

The Company may voluntarily prepay, in whole or in part, the amounts due under the New Oaktree Agreement at any time subject to a prepayment fee. Subject to prior written notice by the Company, to repay any amounts due prior to the maturity date, the Company must pay the sum of (A) the aggregate principal amount of the Loans being prepaid, (B) any accrued but unpaid interest on the principal amount of the Loans being prepaid, (C) any applicable Yield Protection Premium (as defined in the New Oaktree Agreement) and (D) if applicable, other unpaid amounts then due and owing pursuant to the New Oaktree Agreement and the other loan documents (such aggregate amount, the "Prepayment Price"); provided that each partial prepayment of the principal amount of the Loans shall be in an aggregate amount of at least $5.0 million and integral multiples of $1.0 million in excess thereof. The Company is required to make mandatory prepayments of the Loans with net cash proceeds from (i) certain casualty events, (ii) certain monetization events, including, among other things, certain asset sales and the sale(s) of priority review vouchers by certain subsidiaries of the Company, and the receipt by the Company of any dividend or other distributions in cash from any of its subsidiaries in excess of $5.0 million other than in connection with certain monetization events, (iii) debt issuances that are not permitted, and (iv) failure to comply with certain covenants. The lenders may elect to receive warrants to purchase common stock of the Company as an alternative to cash prepayments in some situations where a mandatory prepayment would otherwise be required. No mandatory prepayments were required in the quarter ended September 30, 2024.

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The New Oaktree Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. In addition, the New Oaktree Agreement contains certain financial covenants, including, (i) a requirement that the Company maintain a minimum liquidity of $7.0 million, which may be reduced or increased as described in the New Oaktree Agreement ("the "Liquidity Requirement"), and (ii) that product net sales of Journey meet a consolidated minimum net sales amount of $50.0 million on a trailing 12-month basis, tested quarterly, which may be reduced or increased as described in the New Oaktree Agreement (the "Minimum Net Sales Test"), subject to certain exclusions. Due to the approval of Emrosi, the minimum net sales amount will increase by $7.5 million each quarter, beginning in the third quarter of 2025, provided that the minimum net sales amount will in no event exceed $80.0 million. Both the Minimum Net Sales Test and the Liquidity Requirement will be reduced to $0 while the outstanding principal balance is less than or equal to $10.0 million. The Liquidity Requirement decreases to $5.0 million while the outstanding principal balance is between $10.0 million and $25.0 million. Failure by the Company to comply with the financial covenants will result in an event of default, subject to certain cure rights of the Company with respect to the Minimum Net Sales Test.

The New Oaktree Agreement contains events of default that are customary for financings of this type, in certain circumstances subject to customary cure periods. In addition, the Company is also required to (i) raise common equity, or receive in monetizations or distributions, by the end of each calendar year prior to the maturity date, in an aggregate amount equal to the greater of $20 million or 50% of an amount set forth in an annual budget delivered to the lenders and (ii) maintain a specified minimum equity stake in Journey. The capital raise and minimum stake covenants and financial covenants will not apply if the outstanding principal balance of the loan is less than or equal to $10 million. Following an event of default and any cure period, if applicable, the Agent will have the right upon notice to accelerate all amounts outstanding under the New Oaktree Agreement, in addition to other remedies available to the lenders as secured creditors of the Company.

In connection with the New Oaktree Agreement, the Company granted a security interest in favor of the Agent, for the benefit of the lenders, in substantially all of the Company's assets, subject to customary exceptions, as collateral securing the Company's obligations under the New Oaktree Agreement.

Also in connection with the New Oaktree Agreement, the Company granted warrants to the lenders to purchase up to 506,390 shares of the Company's common stock at a purchase price of $2.0735 per share (the "Warrants"). The Warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offerings and pro rata distributions. The exercise price of the Warrants will also be adjusted if, while the Warrants are outstanding, the Company engages in any transaction involving the issuance or sale of shares of Common Stock or equivalent securities at an effective price per share less than the exercise price of the Warrant then in effect (such lower price, the "Base Share Price"). In such case, the exercise price of the Warrants will be reduced to equal the Base Share Price. The Warrants are exercisable from July 25, 2024 and will expire on July 25, 2031 and may be net exercised for no cash payment at the holder's election. The Company filed a registration statement to register the resale of the shares of Company common stock issuable upon exercise of the Warrants (see Note 13).

The Company was in compliance with all applicable covenants under the New Oaktree Agreement as of September 30, 2024.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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*2020 Oaktree Note*

On July 25, 2024, the Company's $50.0 million outstanding balance of the senior secured credit agreement with Oaktree (the "Prior Oaktree Agreement" and the debt thereunder, the "2020 Oaktree Note") was terminated upon receipt by Oaktree of a payoff amount of $51.4 million from the Company comprised of principal, interest and the applicable final payment amount. The Company recorded a loss on extinguishment of debt of approximately $3.6 million, representing unamortized debt issuance costs and inclusive of a $1.0 million prepayment fee. The payoff of the 2020 Oaktree Note was treated as a debt extinguishment, as the 2024 Oaktree Note originated from a fund group different from the Prior Oaktree Agreement.

The Company had entered the Prior Oaktree Agreement in August 2020. The Prior Oaktree Agreement contained customary representations and warranties and customary affirmative and negative covenants as well as certain financial covenants, including, among other things, (i) maintenance of minimum liquidity and (ii) a minimum revenue test that required Journey's annual revenue to be equal to or to exceed annual revenue projections set forth in the Prior Oaktree Agreement. Failure by the Company or Journey, as applicable, to comply with the Prior Oaktree Agreement covenants would result in an event of default, subject to certain cure rights of the Company.

The Company was required to make quarterly interest-only payments until the fifth anniversary of the closing date of the 2020 Oaktree Note, August 27, 2025, at which point the outstanding principal amount would have been due. The Company could have voluntarily prepaid the 2020 Oaktree Note at any time subject to a prepayment fee. The Company was required to make mandatory prepayments of the 2020 Oaktree Note under various circumstances as defined in the Prior Oaktree Agreement.

*SWK Term Loan*

On December 27, 2023 (the "SWK Closing Date"), Journey entered into a Credit Agreement with SWK Funding LLC ("SWK"). The Credit Agreement provides for a term loan facility (the "Credit Facility") in the original principal amount of up to $20.0 million. On the SWK Closing Date, Journey drew $15 million. On June 26, 2024, Journey drew the remaining $5.0 million under the Credit Facility. Loans under the Credit Facility (the "Term Loans") mature on December 27, 2027. The Term Loans accrue interest which is payable quarterly in arrears. The Term Loans bear interest at a rate per annum equal to the three-month term SOFR (subject to a SOFR floor of 5%) plus 7.75%. The interest rate resets quarterly. Interest payments began in February 2024 and are paid quarterly.

On July 9, 2024, Journey entered into an amendment (the "SWK Amendment") to the Credit Facility. The SWK Amendment increased the total amount available under the Credit Facility from $20.0 million to $25.0 million. The $5.0 million available under the SWK Amendment is contractually required to be drawn upon FDA approval of Journey's DFD-29 product candidate, Emrosi, subject to Journey receiving such approval on or before June 30, 2025. The FDA approved Emrosi on November 4, 2024 (see Note 19).

Beginning in February 2026, Journey is required to repay a portion of the outstanding principal of the Term Loans quarterly in an amount equal to 7.5% of the principal amount of funded Term Loans, with any remaining principal balance due on the maturity date. If the total revenue of Journey, measured on a trailing twelve-month basis, is greater than $70.0 million as of December 31, 2025, the principal repayment start date is extended from February 2026 to February 2027, at which point Journey is required to repay a portion of the outstanding principal of the Term Loans quarterly in an amount equal to 15% of the principal amount of funded Term Loans, with any remaining principal balance due on the maturity date.

Journey may at any time prepay the outstanding principal balance of the Term Loans in whole or in part. Prepayment of the Term Loans is subject to payment of a prepayment premium equal to (i) 2% of the Term Loans prepaid plus the amount of interest that would have been due through the first anniversary of the SWK Closing Date if the Term Loans are prepaid prior to the first anniversary of the SWK Closing Date, (ii) 1% of the Term Loans prepaid if the Term Loans are prepaid on or after the first anniversary of the SWK Closing Date but prior to the second anniversary of the SWK Closing Date, or (iii) 0% if prepaid thereafter.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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Upon repayment in full of the Term Loans, Journey will pay an exit fee equal to 5% of the original principal amount of the Term Loans. Additionally, Journey paid an origination fee of $0.2 million on the SWK Closing Date and incurred issuance costs of $0.2 million, both of which have been recorded as a debt discount. Journey is accreting the carrying value of the SWK Term Loan to the original principal balance plus the exit fee over the term of the loan using the effective interest method. The amortization of the discount is accounted for as interest expense in the Consolidated Statement of Operations. The effective interest rate on the SWK Term Loan as of September 30, 2024 was 14.9%.

The SWK Credit Facility also includes both revenue and liquidity covenants, restrictions as to payment of dividends, and is secured by substantially all assets of Journey. As of September 30, 2024, Journey was in compliance with the financial covenants under the SWK Credit Facility.

*Urica 8% Cumulative Convertible Class B Preferred Offering*

In December 2022 and February 2023, Urica closed private offerings of its 8% Cumulative Convertible Class B Preferred Stock (the "Urica Preferred Stock"), at a price of $25.00 per share ("Subscription Price") pursuant to which it sold a total of 135,494 shares of Urica Preferred Stock for gross proceeds of $3.4 million, before deducting underwriting discounts and commissions and offering expenses of approximately $0.5 million (the "Urica Offering"). A non-cash contingent warrant value of $0.1 million was also recorded in debt discount (see Note 6).

Dividends on the Urica Preferred Stock were payable monthly by Fortress in shares of Fortress common stock based upon a 7.5% discount to the average closing price over the 10-day period preceding the dividend payment date. Dividends were recorded as interest expense. For the three month periods ended September 30, 2024 and 2023, the Company recorded expense of nil and $0.1 million associated with the Urica dividends and for the nine month periods ended September 30, 2024 and 2023, the Company recorded expense of $0.1 million and $0.2 million, respectively, associated with the Urica dividends.

The shares mandatorily converted into Urica common stock upon either: (i) a qualified financing pursuant to which Urica raises at least $20 million in aggregate gross proceeds; or (ii) a sale of Urica. Additionally, in the event that neither such a qualified financing nor a sale of Urica had occurred prior to June 27, 2024, then each holder of Urica Preferred Stock was eligible to receive, at Fortress' election, one of: (x) a cash payment equal to the product of the Subscription Price and the number of shares of Urica Preferred Stock held by such holder; (y) a number of shares of Fortress common stock equal to the Fortress Share Exchange Amount (as defined in the applicable instrument); or (z) a combination of the foregoing. On June 27, 2024, as neither a qualified financing nor a sale of Urica occurred, Fortress elected to exchange the outstanding shares of Urica Preferred Stock, which was recorded as a liability, into 2,028,345 shares of Fortress common stock.

**Interest Expense**

Interest expense includes contractual interest, and fees include amortization of the debt discount and amortization of fees associated with loan transaction costs, amortized over the life of the loan. The following table shows the components of interest expense for all debt arrangements during the periods presented:

| | Three Months Ended September 30, | | | | | |
|---|---|---|---|---|---|---|
| | 2024 | | | 2023 | | |
| *($ in thousands)* | *Interest* | *Fees* | Total | *Interest* | *Fees* | Total |
| 2024 Oaktree Note | 861 | 145 | 1,006 | — | — | — |
| 2020 Oaktree Note | 440 | 159 | 599 | 1,425 | 459 | 1,884 |
| Loss on extinguishment of debt | — | 3,582 | 3,582 | — | — | — |
| Partner company convertible preferred shares | — | — | — | 234 | 140 | 374 |
| Partner company installment payments - licenses | — | — | — | 177 | — | 177 |
| Partner company notes payable | 671 | 87 | 758 | 33 | 58 | 91 |
| Partner company contingent call option accretion | 261 | — | 261 | — | — | — |
| Other | 3 | — | 3 | 8 | — | 8 |
| **Total Interest Expense and Financing Fee** | $ 2,236 | $ 3,973 | $ 6,209 | $ 1,877 | $ 657 | $ 2,534 |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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| | Nine Months Ended September 30, | | | | | |
|---|---|---|---|---|---|---|
| | 2024 | | | 2023 | | |
| *($ in thousands)* | *Interest* | *Fees* | Total | *Interest* | *Fees* | Total |
| 2024 Oaktree Note | 861 | 145 | 1,006 | — | — | — |
| 2020 Oaktree Note | 3,220 | 1,184 | 4,404 | 4,206 | 1,595 | 5,801 |
| Loss on extinguishment of debt | — | 3,582 | 3,582 | — | — | — |
| Partner company convertible preferred shares | (290) | 90 | (200) | 886 | 439 | 1,325 |
| Partner company installment payments - licenses | — | — | — | 353 | — | 353 |
| Partner company notes payable | 1,656 | 212 | 1,868 | 4,834 | 490 | 5,324 |
| Partner company contingent call option accretion | 261 | — | 261 | — | — | — |
| Other | 12 | — | 12 | 120 | 332 | 452 |
| Total Interest Expense and Financing Fee | $ 5,720 | $ 5,213 | $ 10,933 | $ 10,400 | $ 2,856 | $ 13,255 |

**10. Accounts Payable and Accrued Expenses and Partner Company Installment Payments**

Accounts payable and accrued expenses consisted of the following:

| *($ in thousands)* | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Accounts payable | $ 34,030 | $ 34,810 |
| Accrued expenses: | | |
| Professional fees | 2,344 | 1,681 |
| Salaries, bonus and related benefits | 6,064 | 8,531 |
| Research and development | 7,586 | 11,644 |
| Accrued royalties payable | 1,601 | 2,015 |
| Accrued coupon and rebates | 6,321 | 9,987 |
| Return reserve | 3,430 | 4,077 |
| Other | 3,123 | 817 |
| Total accounts payable and accrued expenses | $ 64,499 | $ 73,562 |

**Partner company installment payments – licenses**

In August 2024, Journey executed a settlement agreement (the "Ximino Settlement Agreement") to settle amounts owed by Journey to Sun Pharmaceutical Industries, Inc. ("Sun") pursuant to the Ximino asset purchase agreement. Journey owed $3.0 million of license installment payments to Sun associated with the license of Ximino. Pursuant to the Ximino Settlement Agreement, Journey agreed to settle the total outstanding obligation owed to Sun for a total of $1.9 million, payable in three installments: (1) $0.6 million upon execution of the Ximino Settlement Agreement, (2) $0.6 million on December 1, 2024, and (3) $0.6 million on January 15, 2025. Journey accounted for the settlement of the license installment payment as a gain of $1.1 million for the difference between the carrying value of the license installment payments of $3.0 million and the settlement amount of $1.9 million. The Company recorded the difference of $1.1 million as a gain on extinguishment of debt, which is included in Other income on the unaudited condensed consolidated statements of operations.

**11. Non-Controlling Interests**

The Company's ownership interests in its consolidated subsidiaries at September 30, 2024 was similar to December 31, 2023, except for Mustang which decreased from 19.0% to 7.4%.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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**12. Net Loss per Common Share**

Basic and diluted net loss per share attributed to common stockholders is calculated by dividing the net loss attributed to Fortress, less the Series A Preferred dividends and adjusted for subsidiary deemed dividends, by the weighted-average number of shares of Common Stock outstanding during the period, not including unvested restricted stock, and without consideration for Common Stock equivalents. Diluted net loss per share is the same as the basic loss per share due to net losses in all periods.

For the three and nine months ended September 30, 2024, the effect on the net loss per share calculation from Series A Preferred dividends was $2.0 million and $6.0 million, respectively, and partner company deemed dividends were $0.2 million and $1.0 million, respectively. For the three and nine months ended September 30, 2023, the effect on the net loss per share calculation from Series A Preferred dividends was $2.0 million and $6.0 million, respectively, and partner company deemed dividends were $0.1 million and $0.4 million, respectively.

For the three and nine months ended September 30, 2024 and 2023, diluted and basic net loss per share attributable to common stockholders of the Company were identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive. nine months ended September 30, 2024 and 2023, the following potentially dilutive common stock equivalents were excluded from the computation of net loss per common share:

| | September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Warrants to purchase Common Stock | 14,499,535 | 127,296 |
| Options to purchase Common Stock | 558,896 | 160,233 |
| Unvested Restricted Stock | 1,628,082 | 1,338,750 |
| Unvested Restricted Stock Units | 166,160 | 106,708 |
| Total | 16,852,673 | 1,732,987 |

**13. Stockholders' Equity**

*9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Dividends*

On July 5, 2024, Fortress announced that the Company's Board of Directors had decided to pause the monthly dividend of $0.1953125 per share of the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock"). In accordance with the terms of the Series A Preferred Stock, dividends on the Series A Preferred Stock will continue to accrue and cumulate until such dividends are authorized or declared. The pausing of these dividends will defer approximately $0.7 million in cash dividend payments each month. The Board intends to revisit its decision regarding the monthly dividend regularly and will assess the profitability and cash flow of the Company to determine whether and when the pause should be lifted.

During the three months ended September 30, 2024, no dividends were declared by the Board of Directors. At September 30, 2024, the Company had total undeclared dividends of approximately $2.0 million, which represents the cumulated (but undeclared) dividends due to Series A Preferred shareholders on September 30, 2024. Dividends in arrears that have not been declared by the Board of Directors are not recorded in the condensed consolidated balance sheets but are reflected in the net loss attributable to common shareholders (see Note 12).

**Stock-based Compensation**

As of September 30, 2024, the Company had the following equity compensation plans: the Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended (the "2013 Plan"), the Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan (the "ESPP") and the Fortress Biotech, Inc. Long Term Incentive Plan ("LTIP"). In May 2024, the Company's Board of Directors and stockholders approved an amendment to the 2013 Plan to increase the number of authorized shares issuable by 10.0 million shares, and approved an amendment to the ESPP to increase the number of shares issuable by 1.0 million. As of September 30, 2024, approximately 10.0 million shares are available for issuance under the 2013 Plan, and approximately 1.0 million shares are available for issuance under the ESPP.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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The following table summarizes the stock-based compensation expense from stock option, employee stock purchase programs and restricted Common Stock awards and warrants for the periods presented:

| *($ in thousands)* | Three Months Ended September 30, 2024 | Three Months Ended September 30, 2023 | Nine Months Ended September 30, 2024 | Nine Months Ended September 30, 2023 |
|---|---|---|---|---|
| Fortress: | | | | |
| Employee and non-employee awards | $ 2,385 | $ 2,077 | $ 6,827 | $ 6,785 |
| Executive awards | 276 | 385 | 772 | 1,202 |
| Partner Companies: | | | | |
| Avenue | 331 | 561 | 714 | 599 |
| Checkpoint | 1,611 | 689 | 3,491 | 2,225 |
| Mustang | 42 | 100 | (500) | 380 |
| Journey | 1,640 | 558 | 4,720 | 2,077 |
| Other | 288 | 7 | 405 | 57 |
| Total stock-based compensation expense | $ 6,573 | $ 4,377 | $ 16,429 | $ 13,325 |

For the three months ended September 30, 2024 and 2023, approximately $1.2 million and $0.9 million, respectively, of stock-based compensation expense was included in research and development expenses in connection with equity grants made to employees and consultants and approximately $5.4 million and $3.5 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

For the nine months ended September 30, 2024 and 2023, approximately $2.9 million and $2.3 million, respectively, of stock-based compensation expense was included in research and development expenses in connection with equity grants made to employees and consultants and approximately $13.5 million and $11.0 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

*Stock Options*

The following table summarizes Fortress stock option activities excluding activity related to Fortress subsidiaries and partner companies:

| | Number of shares | Weighted average exercise price | Total weighted average intrinsic value | Weighted average remaining contractual life (years) |
|---|---|---|---|---|
| Options vested and expected to vest at December 31, 2023 | 18,896 | $ 20.55 | $ — | 1.76 |
| Granted | 540,000 | 1.68 | — | 6.45 |
| Options vested and expected to vest at September 30, 2024 | 558,896 | $ 2.32 | $ — | 6.27 |
| Options vested and exercisable at September 30, 2024 | 18,896 | $ 20.55 | $ — | 1.01 |

As of September 30, 2024 and 2023, Fortress had $0.6 million and $0.4 million, respectively, in unrecognized stock-based compensation expense related to options which is expected to be recognized over the remaining weighted-average vesting period of 3.3 years and 2.7 years, respectively.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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*Restricted Stock and Restricted Stock Units*

The following table summarizes Fortress restricted stock awards and restricted stock units activities, excluding activities related to Fortress subsidiaries and partner companies:

| | Number of shares | Weighted average grant price |
|---|---|---|
| Unvested balance at December 31, 2023 | 1,458,700 | $ 28.05 |
| Restricted stock granted | 443,025 | 3.01 |
| Restricted stock vested | (22,969) | 35.67 |
| Restricted stock units granted | 37,500 | 39.61 |
| Restricted stock units forfeited | (19,485) | 14.56 |
| Restricted stock units vested | (102,529) | 39.61 |
| Unvested balance at September 30, 2024 | 1,794,242 | $ 21.49 |

As of September 30, 2024 and 2023, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $6.5 million and $13.5 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 1.0 years and 1.7 years, respectively.

*Warrants*

The following table summarizes Fortress warrant activities, excluding activities related to Fortress subsidiaries and partner companies:

| | Number of shares | Weighted average exercise price | Total weighted average intrinsic value | Weighted average remaining contractual life (years) |
|---|---|---|---|---|
| Outstanding as of December 31, 2023 | 5,787,289 | $ 1.88 | $ 7,794,450 | 4.91 |
| Issued | 8,729,746 | 2.35 | — | — |
| Exercised | (17,500) | 1.70 | — | — |
| Outstanding as of September 30, 2024 | 14,499,535 | $ 2.16 | $ — | 4.71 |
| Exercisable as of September 30, 2024 | 14,499,535 | $ 2.16 | $ — | 4.71 |

In connection with the 2024 Oaktree Note (see Note 9), the Company issued warrants to Oaktree and certain of its affiliates to purchase up to approximately 0.5 million shares of Common Stock at a purchase price of $2.0735 per share (the "2024 Oaktree Warrants"). Oaktree is entitled to a reduction in exercise price if, at any time prior to the expiration of the 2024 Oaktree Warrants, the Company issues equity, warrants or convertible notes (collectively known as "Security Instruments") at a price that is less than 95% of the market price of the Company's Common Stock on the trading day prior to the issuance of the Security Instruments. As a result of the September 2024 registered direct offering (see Note 13), the exercise price on the 2024 Oaktree warrants was lowered to $1.65 per share, and recorded approximately $20,000 expense to interest expense.

The Company evaluated the accounting treatment of the 2024 Oaktree Warrants and determined that the 2024 Oaktree warrants met the scope exception of *ASC 815-10-15-74(a) Derivatives and Hedging* and therefore the warrants should be classified in stockholders' equity. As such, the Company used a Black-Scholes model to value the Oaktree Warrants. Utilizing the following inputs: term of 7 years, volatility of 90.52%, risk-free rate of return of 4.18% yielding a value of $1.3 million. *ASC 470-20-25-2 Debt – Debt with Conversion and Other Options* dictates that debt or stock issued with detachable warrants requires the proceeds to be allocated to the two instruments based on their relative fair values. The relative fair value of the warrants was determined to be $1.3 million and was recorded as a component of Stockholders' Equity in the Company's condensed consolidated balance sheet at September 30, 2024.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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In connection with the 2020 Oaktree Note (see Note 9), in August 2020 the Company had issued warrants to Oaktree and certain of its affiliates to purchase up to approximately 0.1 million shares of Common Stock at an exercise price of $8.14 per share (the "Oaktree Warrants"). The Oaktree Warrants expire on August 27, 2030 and may be net exercised at the holder's election. Oaktree is entitled to additional warrants if at any time prior to the expiration of the Oaktree Warrants the Company issues equity, warrants or convertible notes (collectively known as "Security Instruments") at a price that is less than 95% of the market price of the Company's Common Stock on the trading day prior to the issuance of the Security Instruments. As a result of the September 2024 registered direct offering (see Note 13), the Company issued an additional 14,450 warrants to Oaktree and adjusted the exercise price of the Oaktree Warrants to $7.2392, and recorded the resulting expense of $27,000 to interest expense.

The Company filed registration statement No. 333-282384 on Form S-1 to register the resale of the shares of Common Stock issuable upon exercise of the 2024 Oaktree Warrants and the additional Oaktree Warrants, which was declared effective by the SEC on October 7, 2024.

*Long-Term Incentive Program ("LTIP")*

On July 15, 2015, the Company's stockholders approved the LTIP for the Company's Chairman, President and Chief Executive Officer, Dr. Rosenwald, and Executive Vice Chairman, Strategic Development, Mr. Weiss (amended and restated with stockholder approval on June 7, 2017 and May 23, 2024). The LTIP consists of a program to grant equity interests in the Company and in the Company's subsidiaries, and a performance-based bonus program that is designed to result in performance-based compensation that is deductible without limit under Section 162(m) of the Internal Revenue Code of 1986, as amended.

On January 1, 2024 and 2023, the Compensation Committee granted 216,465 shares and 81,286 shares each to Dr. Rosenwald and Mr. Weiss, respectively. These equity grants were made in accordance with the LTIP, and each award represents 1% of total outstanding shares of the Company as of the dates of such grants. The shares' original vesting terms includes vesting in full if the employee was either in the service of the Company as an employee, Board member or consultant (or any combination of the foregoing) on the tenth anniversary of the LTIP, or the eligible employee has an involuntary Separation from Service (as defined in the LTIP). The only other vesting condition – one based on the achievement of an increase in the Company's market capitalization – has already been achieved, with respect to each annual award under the LTIP. The shares awarded under the LTIP will also vest in full (and the Company's repurchase option on each tranche of shares granted thereunder will accordingly lapse) upon the occurrence of a Corporate Transaction (as defined in the LTIP), if the eligible employee is in service to the Company on the date of such Corporate Transaction. The fair value of each grant on the grant date was approximately $0.7 million for the 2024 grant and $0.8 million for the 2023 grant. For the three months ended September 30, 2024 and 2023, the Company recorded stock compensation expense related to LTIP grants of approximately $1.7 million and $1.5 million, respectively, and for the nine months ended September 30, 2024 and 2023, the Company recorded stock compensation expense related to LTIP grants of approximately $5.0 million and $4.4 million, respectively, on the unaudited condensed consolidated statement of operations.

**Capital Raises**

***2024 Shelf***

On May 17, 2024, the Company filed a shelf registration statement (File No. 333-279516) on Form S-3, which was declared effective on May 30, 2024 (the "2024 Shelf"). As of September 30, 2024, $43.5 million of securities were available for sale under the 2024 Shelf, subject to General Instruction I.B.6. of Form S-3, known as the "baby shelf rules," which limit the number of securities that can be sold under registration statements on Form S-3.

On July 23, 2021, the Company filed a shelf registration statement (File No. 333-258145) on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). As of September 30, 2024, there were no securities available for sale under the 2021 Shelf as the ability of the Company to register new offers and sales of securities under the 2021 Shelf expired.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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***At the Market Offering***

During the nine months ended September 30, 2024, the Company issued and sold approximately 1.8 million shares at an average price of $1.95 per share for gross proceeds of $3.5 million under the Company's at-the-market offering program. During the nine months ended September 30, 2023, the Company issued and sold approximately 0.2 million shares at an average price of $9.61 for gross proceeds of $2.2 million under the Company's at-the-market offering program.

***Equity Offerings and Private Placements***

In September 2024, Fortress closed a registered direct offering of an aggregate of 3,939,394 shares of its common stock at a purchase price of $1.65 per share. In a concurrent private placement, the Company also agreed to issue to the same investors that participated in the registered direct offering warrants to purchase up to 3,939,394 shares of common stock (the "Private Placement Warrants"). The Private Placement Warrants have an exercise price of $1.84 per share, will be exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issue.

In a separate concurrent private placement, Dr. Rosenwald purchased 763,359 shares of common stock at a price of $1.84 per share, which represented the consolidated closing bid price of the Company's common stock on the Nasdaq Capital Market on September 19, 2024, and warrants to purchase up to 763,359 shares of common stock, purchased at a price of $0.125 per warrant (the "(Concurrent Private Placement Warrants"). The Concurrent Private Placement Warrants have an exercise price of $1.84 per share, will be exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issue. Net proceeds to Fortress from the September 2024 registered direct offering and the concurrent private placements, after deducting the placement agent's fees and other offering expenses and assuming no exercises of the Private Placement Warrants or the Concurrent Private Placement Warrants, were approximately $7.4 million.

The Company filed registration statement No. 333-282384 on Form S-1 to register the resale of the shares of Common Stock issuable upon exercise of the Private Placement Warrants and the Concurrent Private Placement Warrants, which was declared effective by the SEC on October 7, 2024.

In connection with the financing consummated by the Company in September 2024, the 5,885,000 warrants issued in the November 2023 equity offering (the "November 2023 Warrants") had their exercise price reduced to $1.65 per share. The November 2023 Warrants contained a one-time exercise price adjustment provision that reduced the exercise price upon the next equity financing at a price lower than the exercise price at issuance which was $1.70 per share.

In January 2024, Fortress closed a registered direct offering of an aggregate of 3,303,305 shares of its common stock and warrants to purchase up to 3,303,305 shares of its common stock at a combined purchase price of $3.33 per share of common stock and accompanying warrant priced at-the-market under Nasdaq rules. The warrants have an exercise price of $3.21 per share, were immediately exercisable, and expire five years following the date of issue. Net proceeds to Fortress, after deducting the placement agent's fees and other offering expenses, were approximately $10.2 million.

***Checkpoint 2023 Shelf Registration Statement***

In March 2023, Checkpoint filed a shelf registration statement (File No. 333-270843) on Form S-3 (the "Checkpoint 2023 S-3"), which was declared effective May 5, 2023. Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of September 30, 2024, approximately $65.7 million of the securities remains available for sale through the Checkpoint 2023 S-3.

In November 2020, Checkpoint filed a shelf registration statement (File No. 333-251005) on Form S-3, which was declared effective in December 2020 (the "Checkpoint 2020 S-3"). As of September 30, 2024, there were no securities available for sale under the Checkpoint 2020 S-3 as the ability of Checkpoint to register new offers and sales of securities under the Checkpoint 2020 S-3 expired.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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***Checkpoint Registered Direct Offerings***

In July 2024, Checkpoint closed on a registered direct offering (the "Checkpoint July 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,230,000 shares of its common stock at a purchase price of $2.05 per share of common stock. In addition, the offering includes 4,623,659 shares of common stock in the form of pre-funded warrants at a price of $2.0499. In a concurrent private placement, Checkpoint issued and sold common warrants (the "Checkpoint July 2024 Common Stock Warrants") to purchase up to 5,853,659 shares of common stock. The Checkpoint July 2024 Common Stock Warrants will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Checkpoint July 2024 Common Stock Warrants with an exercise price of $2.05 per share and will expire five years following the issuance date. Checkpoint also issued the placement agent warrants to purchase up to 351,220 shares of common stock with an exercise price of $2.5625 per share. The total net proceeds from the July 2024 Registered Direct Offering, after deducting placement agent's fees and other offering expenses, were approximately $11.0 million.

In January 2024, Checkpoint closed on a registered direct offering (the "Checkpoint January 2024 Registered Direct Offering") for the issuance and sale of 1,275,000 shares of its common stock and 6,481,233 pre-funded warrants. Each pre-funded warrant was exercisable for one share of Checkpoint common stock. The Checkpoint common stock and the pre-funded warrants were sold together with common stock warrants (the "Checkpoint January 2024 Common Warrants") to purchase up to 7,756,233 shares of Checkpoint common stock, at a purchase price of $1.805 per share of common stock and $1.8049 per pre-funded warrant. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001 and are exercisable commencing on the closing date and will terminate when such pre-funded warrants are exercised in full. The Checkpoint January 2024 Common Warrants are exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of $1.68 per share. Checkpoint also issued the placement agent warrants to purchase up to 465,374 shares of common stock with an exercise price of $2.2563 per share. Net proceeds to Checkpoint from the Checkpoint January 2024 Registered Direct Offering were $12.6 million after deducting commissions and other transaction costs. All of the pre-funded warrants from the Checkpoint January 2024 Registered Direct Offering are fully exercised.

Pursuant to the Company's Founders Agreement with Checkpoint, Checkpoint issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the registered direct offerings noted above. Accordingly, Checkpoint issued 340,246 shares of common stock to Fortress for the nine months ended September 30, 2024.

***Avenue 2021 Shelf Registration Statement***

In December 2021, Avenue filed a shelf registration statement (File No. 333-261520) on Form S-3 (the "Avenue 2021 S-3"), which was declared effective on December 10, 2021. As of September 30, 2024, approximately $24.1 million of the securities were available for sale under the Avenue 2021 S-3, subject to General Instruction I.B.6. of Form S-3.

***Avenue 2024 Warrant Exercises and Private Placement***

On January 5, 2024, Avenue entered into (i) an inducement offer letter agreement (the "January 2023 Investor Inducement Letter") with a certain investor (the "January 2023 Investor") in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 shares of Common Stock, originally issued to the January 2023 Investor on January 31, 2023 (the "January 2023 Warrants") and (ii) an inducement offer letter agreement (the "November 2023 Investor Inducement Letter Agreement" and, together with the January 2023 Investor Inducement Letter, the "January 2024 Warrant Inducement") with certain investors (the "November 2023 Investors" and, together with the January 2023 Investor, the "Holders") in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of Common Stock, originally issued to the November 2023 Investors on November 2, 2023 (the "November 2023 Warrants" and, together with the January 2023 Warrants, the "Existing Warrants"). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise its January 2023 Warrants for cash at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise their November 2023 Warrants for cash at the existing exercise price of $22.545, in each case in consideration for Avenue's agreement to issue in a private placement (x) Series A Warrants to purchase up to 220,538 shares of Avenue Common Stock and (y) Series B Warrants to purchase up to 220,538 shares of Avenue Common Stock. The net proceeds to Avenue from the exercise of the warrants was approximately $4.5 million, after deducting placement agent fees and estimated offering costs, but without giving effect to the exercise of the Series A Warrants and Series B Warrants issued in the January 2024 Warrant Inducement.

The fair value of the Series A Warrants and Series B Warrants was allocated between the January 2023 Warrants and the November 2023 Warrants on a weighted basis, with approximately $0.6 million allocated to the January 2023 Warrants and recorded to loss on common stock warrant liabilities in the condensed consolidated statement of operations, and the approximately $4.3 million allocated to the November 2023 Warrants deemed to be a dividend such that it was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statement of operations (see Note 12).

Also in April 2024, Avenue entered into definitive agreements for the immediate exercise of certain of its existing outstanding warrants for cash an aggregate of 689,680 warrants for shares of Avenue's common stock at a reduced exercise price of $6.20 per share (the "May 2024 Warrant Inducement"). The exercised warrants are comprised of warrants to purchase shares of common stock originally issued by Avenue on October 11, 2022, each having an exercise price of $116.25 per share, Series A and Series B warrants to purchase shares of common stock originally issued by Avenue on November 2, 2023, each having an exercise price of $22.545 per share, and warrants to purchase shares of common stock originally issued by Avenue on January 9, 2024, each having an exercise price of $22.545 per share. Total net proceeds to Avenue were approximately $3.7 million after deducting placement agent fees and other expenses payable by Avenue.

In consideration for the immediate exercise of the warrants for cash in the May 2024 Warrant Inducement, Avenue issued two new unregistered series of warrants (the "Avenue May 2024 Warrants") to purchase up to a total of 1,379,360 shares of Avenue common stock for a payment of $0.125 per warrant. The Avenue May 2024 Warrants have an exercise price of $6.20 per share, and terms of eighteen months for one series and five years for the other series. The fair value of the Avenue May 2024 Warrants of approximately $4.5 million is deemed to be a dividend such that it was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statement of operations (see Note 12).

In May 2024, Avenue entered into an At-the-Market Offering Agreement (the "Avenue ATM") under which Avenue may offer and sell, from time to time at its sole discretion, up to $3.9 million of shares of its common stock. The offer and sale of the shares will be made pursuant to a base prospectus forming a part of the 2021 Avenue S-3, and the related prospectus supplement dated May 10, 2024. During the nine months ended September 30, 2024, Avenue issued 245,617 shares through the Avenue ATM for net proceeds of $0.9 million.

Pursuant to the Company's Founders Agreement with Avenue, Avenue issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the warrant exercises noted above. Accordingly, Avenue issued 25,567 shares of common stock to Fortress and recorded 4,023 shares issuable to Fortress for the nine-month period ended September 30, 2024.

***Mustang 2021 Shelf Registration Statement and At-the-Market Offering (the "Mustang ATM")***

On April 23, 2021, Mustang filed a shelf registration statement on Form S-3 (File No. 333-255476) (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Under the Mustang 2021 S-3, Mustang was able to sell up to a total of $200.0 million of its securities. In 2024, Mustang sold approximately $4.4 million of securities under the Mustang 2021 S-3 until Mustang's ability to register new offers and sales of securities under such registration statement expired on May 24, 2024.

On May 31, 2024, Mustang filed a shelf registration statement on Form S-3 (File No. 333-279891) (the "Mustang 2024 S-3"), which was declared effective on June 12, 2024. Under the Mustang 2024 S-3, Mustang may sell up to a total of $40.0 million of its securities. As of September 30, 2024, approximately $36.3 million of the Mustang 2024 S-3 remains available for sales of securities, subject to General Instruction I.B.6. of Form S-3. The ability of Mustang to register new offers and sales of securities under the Mustang 2024 S-3 expires on June 12, 2027.

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On May 31, 2024, Mustang entered into an At-the-Market Offering Agreement (the "Mustang ATM") relating to the sale of shares of common stock pursuant to the Mustang 2024 S-3. During the nine months ended September 30, 2024, Mustang issued approximately 2.7 million shares through the Mustang ATM for net proceeds of approximately $1.2 million.

***Mustang Equity Offering***

In May 2024, Mustang closed on an equity offering of 1,160,000 shares of common stock and pre-funded warrants to purchase up to 15,717,638 shares of common stock (or common stock equivalents in lieu thereof), and three series of 16,877,638 warrants each for a total of 50,632,914 warrants with a combined equity offering price of $0.237 per share (or per share common stock equivalent in lieu thereof) and accompanying warrants with an exercise price of $0.237 per share. The Series A-1 warrants have a five-year term, the Series A-2 warrants have a twenty-four month term, and the Series A-3 warrants have a nine month term. The warrants contain customary anti-dilution adjustments to the exercise price, including share splits, share dividends, rights offerings and pro rata distributions. The net proceeds of the equity offering, after deducting the fees and expenses of the placement agent and other offering expenses payable by Mustang was approximately $3.2 million. All of the 15,717,638 pre-funded warrants have since been exercised.

Mustang also amended certain existing warrants to purchase up to 2,588,236 shares of common stock previously issued in October 2023 with an exercise price of $1.58 per share such that the amended warrants have a reduced exercise price of $0.237 per share, and have a five-year term from date of shareholder approval.

***Mustang Registered Direct Offering***

In June 2024, Mustang closed on a registered direct offering of 3,025,000 shares of common stock at $0.41 per share (or common stock equivalent) priced at-the-market under Nasdaq rules and pre-funded warrants to purchase up to 3,105,000 shares of common stock, at a price per pre-funded warrant equal to $0.4099, the price per share of common stock, less $0.001. The pre-funded warrants have an exercise price of $0.001 per share, became exercisable upon issuance and remain exercisable until exercised in full. In a concurrent private placement, Mustang also agreed to issue and sell unregistered warrants to purchase up to 6,130,000 shares of its common stock, with an exercise price of $0.41 per share, exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the warrants and will expire five years from the date of stockholder approval. Net proceeds were approximately $2.1 million, after placement agent's fees and other offering expenses. All of the 3,105,000 pre-funded warrants have since been exercised.

Pursuant to the Company's Founders Agreement with Mustang, Mustang issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the financings noted above. Accordingly, Mustang issued 641,740 shares of common stock to Fortress for the nine-month period ended September 30, 2024.

***Journey 2022 Shelf Registration Statement and At-the-Market Offering***

On December 30, 2022, Journey filed a shelf registration statement on Form S-3 (File No. 333-269079) (the "Journey 2022 S-3"), which was declared effective on January 26, 2023. The Journey 2022 S-3 covers the offering, issuance and sale by Journey of up to an aggregate of $150.0 million of Journey's common stock, preferred stock, debt securities, warrants, and units. In connection with the Journey 2022 S-3, Journey entered into a sales agreement relating to the sale of shares of Journey's common stock in an at-the-market offering (the "Journey ATM Sales Agreement"). In accordance with the terms of the Journey ATM Sales Agreement, Journey may offer and sell up to 4,900,000 shares of its common stock, par value $0.0001 per share, from time to time. For the nine months ended September 30, 2024, Journey issued and sold approximately 0.3 million shares of common stock for gross proceeds of $1.7 million under the Journey ATM Sales Agreement. At September 30, 2024, 3.8 million shares remain available for issuance under the Journey ATM Sales Agreement.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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## 14. Commitments and Contingencies

### Leases

During the nine months ended September 30, 2024, Mustang identified triggering events that required an impairment of the asset group consisting of its' right-of-use asset and associated leasehold improvements. The assessment concluded that impairment existed, and the impairment loss was allocated to the leasehold improvements and right-of-use assets based on the relative carrying amounts of the assets (see Note 3).

During three and nine months ended September 30, 2024 and 2023, the Company recorded the following as lease costs for the periods presented:

| *($ in thousands)* | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Operating lease cost | $ 762 | $ 687 | $ 1,997 | $ 2,656 |
| Shared lease costs | (530) | (526) | (1,571) | (1,560) |
| Variable lease cost | 238 | 220 | 628 | 620 |
| Total lease expense | $ 470 | $ 381 | $ 1,054 | $ 1,716 |

The following tables summarize quantitative information about the Company's operating leases, under the adoption of ASC Topic 842*, Leases*:

| *($ in thousands)* | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Operating cash flows from operating leases | $ (2,744) | $ (2,652) |
| Right-of-use assets exchanged for new operating lease liabilities | $ — | $ (923) |
| Weighted-average remaining lease term – operating leases (years) | 3.9 | 4.2 |
| Weighted-average discount rate – operating leases | 6.1 % | 6.3 % |

| *($ in thousands)* | Future Lease Liability |
|---|---|
| Nine Months Ended December 31, 2024 | $ 926 |
| Year Ended December 31, 2025 | 3,541 |
| Year Ended December 31, 2026 | 3,272 |
| Year Ended December 31, 2027 | 2,923 |
| Year Ended December 31, 2028 | 2,966 |
| Other | 8,125 |
| Total operating lease liabilities | 21,753 |
| Less: present value discount | (3,947) |
| Net operating lease liabilities, short-term and long-term | $ 17,806 |

### Indemnification

In accordance with its certificate of incorporation, bylaws and indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance to address such claims. The Company and its subsidiaries and partner companies also provide indemnification of contractual counterparties (sometimes without monetary caps) to clinical sites, service providers and licensors.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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**Legal Proceedings**

In the ordinary course of business, the Company and its subsidiaries and partner companies may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeing resulting alleged damages.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
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*University of Tennessee Research Foundation v. Caelum Biosciences, Inc.*

Caelum Biosciences, Inc. ("Caelum"), a former subsidiary of Fortress that was sold to AstraZeneca's Alexion Pharmaceuticals, Inc. subsidiary ("Alexion") in October 2021, was the defendant in a lawsuit brought by The University of Tennessee Research Foundation ("UTRF") captioned as *University of Tennessee Research Foundation v. Caelum Biosciences, Inc.*, No. 19-cv-00508, which was formerly pending in the United States District Court for the Eastern District of Tennessee (the "UTRF Litigation"). UTRF brought claims against Caelum, for, *inter alia*, trade secret misappropriation. UTRF primarily alleged that Caelum unauthorizedly used non-patent trade secrets owned by UTRF in the development of Caelum's 11-1F4 monoclonal antibody, known as CAEL-101. Under the agreement pursuant to which Alexion acquired Caelum (as amended, the "DOSPA"), Fortress had certain indemnification obligations of Caelum pertaining to the UTRF litigation and maintained a consent right over any potential settlements of the UTRF litigation by Caelum.

On September 16, 2024, Caelum and UTRF entered into a stipulation with the court pursuant to which UTRF's claims were dismissed without prejudice; on October 16, 2024, Caelum and UTRF entered into a definitive settlement agreement (the "UTRF-Caelum Settlement Agreement") pursuant to which UTRF's claims were dismissed with prejudice and Caelum agreed to make an upfront payment and additional potential milestone-based payments to UTRF. Fortress and the other sellers under the DOSPA are explicit releasees and third party beneficiaries under the UTRF-Caelum Settlement Agreement. In connection with the execution of the UTRF-Caelum Settlement Agreement, Caelum, Alexion and Fortress entered into an amendment to the DOSPA (the "DOSPA Amendment"), which, *inter alia*: (1) terminated any continuing indemnification by Fortress and the other sellers under the DOSPA in respect of the UTRF Litigation; (2) reduced the amounts of the potential future earn-out payments potentially owing to the sellers under the DOSPA (including Fortress) from an aggregate amount up to $350 million to an aggregate amount up to $295 million; (3) released to Caelum all amounts remaining in an escrow fund that had been established at the time of the Alexion acquisition to backstop potential indemnifiable damages, including those incurring under the UTRF Litigation (with 100% of such released amount constituting reimbursement for legal fees and other expenses incurred by Caelum in defending the UTRF Litigation); and (4) memorialized Fortress' consent for Caelum to settle the UTRF Litigation. Neither the UTRF-Caelum Settlement Agreement nor the DOSPA Amendment implicates any out-of-pocket payment by Fortress or any other seller under the DOSPA. Fortress remains eligible to receive approximately $19 million upon regulatory approval of CAEL-101 and approximately $125 million in the aggregate across all remaining regulatory and sales milestones.

**15. Related Party Transactions**

*Founders Agreement*

The Company has entered into Founders Agreements and, in some cases, exchange agreements with certain of its subsidiaries as described in the 2023 Form 10-K. The following table summarizes, by partner company/subsidiary, the effective date of the Founders Agreements and Payment-in-Kind ("PIK") dividend or equity fee payable to the Company in accordance with the terms of the Founders Agreements, exchange agreements, and the subsidiaries' certificates of incorporation:

| Partner Company/Subsidiary | Effective Date [1] | PIK Dividend as a % of fully diluted outstanding capitalization | Class of Stock Issued |
|---|---|---|---|
| Avenue | February 17, 2015 | 2.5 % | Common Stock |
| Cellvation | October 31, 2016 | 2.5 % | Common Stock |
| Checkpoint | March 17, 2015 | - %[2] | Common Stock |
| Cyprium | March 13, 2017 | 2.5 % | Common Stock |
| Helocyte | March 20, 2015 | 2.5 % | Common Stock |
| Mustang | March 13, 2015 | 2.5 % | Common Stock |
| Oncogenuity | April 22, 2020 [3] | 2.5 % | Common Stock |
| Urica | November 7, 2017 [3] | 2.5 % | Common Stock |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

Note 1: Represents the effective date of each subsidiary's Founders Agreement. Each PIK dividend and equity fee is payable on the annual anniversary of the effective date of the original Founders Agreement or has since been amended to January 1 of each calendar year.
Note 2: Instead of a PIK dividend, Checkpoint pays the Company an annual equity fee in shares of Checkpoint's common stock equal to 2.5% of Checkpoint's fully diluted outstanding capitalization.
Note 3: Represents the Trigger Date, the date that the Fortress partner company/subsidiary first acquires, whether by license or otherwise, ownership rights in a product.

*Management Services Agreements*

The Company has entered into Management Services Agreements (the "MSAs") with certain of its partner companies/subsidiaries as described in the 2023 Form 10-K. The following table summarizes the effective date of each MSA and the annual consulting fee payable by the partner company/subsidiary to the Company in quarterly installments:

| Partner Company/Subsidiary | Effective Date | Annual MSA Fee (Income)/Expense |
|---|---|---|
| Avenue | February 17, 2015 | 500 |
| Cellvation | October 31, 2016 | 500 |
| Checkpoint | March 17, 2015 | 500 |
| Cyprium | March 13, 2017 | 500 |
| Helocyte | March 20, 2015 | 500 |
| Mustang | March 13, 2015 | 500 |
| Oncogenuity | February 10, 2017 | 500 |
| Urica | November 7, 2017 | 500 |
| Fortress | | (4,000) |
| Consolidated (Income)/Expense | | $ — |

*Fees and Stock Grants Received by Fortress*

Fees recorded in connection with Fortress' agreements with its subsidiaries and partner companies are eliminated in consolidation. These include management services fees, issuance of common shares of partner companies in connection with third party raises and annual stock dividend or issuances on the anniversary date of respective Founders Agreements.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

*Shared Services Agreement with TG Therapeutics, Inc. ("TGTX")*

In July 2015, TGTX and the Company entered into an arrangement to share the cost of certain research and development employees. The Company's Executive Vice Chairman, Strategic Development, is also Executive Chairman and Chief Executive Officer of TGTX. Under the terms of the Agreement, TGTX reimburses the Company for the salary and benefit costs associated with these employees based upon actual hours worked on TGTX related projects. In connection with the shared services agreement, for the three months ended September 30, 2024 and 2023 the Company invoiced TGTX $0.1 million and $0.1 million, respectively; for the nine months ended September 30, 2024 and 2023 invoiced TGTX $0.8 million and $0.3 million, respectively. At September 30, 2024, approximately $36,000 was due from TGTX related to this arrangement.

*Shared Services Agreement with Journey*

On November 12, 2021, Journey and the Company entered into an arrangement to share the cost of certain legal, finance, regulatory, and research and development employees. The Company's Executive Chairman and Chief Executive Officer is also the Executive Chairman of Journey. Under the terms of the arrangement, Journey began reimbursing the Company for the salary and benefit costs associated with these employees based upon actual hours worked on Journey related projects following the completion of their initial public offering in November 2021. In addition, Journey reimburses the Company for various payroll-related costs and selling, general and administrative costs incurred by Fortress for the benefit of Journey. For the three months ended September 30, 2024 and 2023, the Company's employees have provided services to Journey totaling approximately $8,000 and $11,000, respectively. For the nine months ended September 30, 2024 and 2023, the Company's employees have provided services to Journey totaling approximately $26,000 and $47,000, respectively. At September 30, 2024, the total related party receivable was $0.4 million, and primarily relates to reimbursable expenses incurred by Fortress on behalf of Journey.

*Desk Share Agreement with TGTX*

The Desk Share Agreement with TGTX, as amended, requires TGTX to pay its share of the average annual rent for office space in New York, NY, based on the actual percentage of the office space occupied by TGTX on a month-by-month basis. For the three months ended September 30, 2024 and 2023, the Company had paid $0.7 million and $0.6 million in rent, respectively, and in connection with the Company's Desk Share Agreement with TGTX, has invoiced TGTX approximately $0.5 million and $0.5 million, respectively, for its prorated share of the rent base. For the nine months ended September 30, 2024 and 2023, the Company had paid $2.2 million and $1.5 million in rent, respectively, and in connection with the Company's Desk Share Agreement with TGTX, has invoiced TGTX approximately $1.4 million and $1.4 million, respectively, for its prorated share of the rent base. At September 30, 2024, there was no balance due from TGTX related to this arrangement.

*Cyprium 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Dividend Obligation*

Pursuant to a private placement in August 2020, Cyprium sold 320,000 shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Cyprium PPS"); as of September 30, 2024, there remain 320,000 shares of Cyprium PPS outstanding. The Cyprium PPS is fully and unconditionally guaranteed by Fortress.

Pursuant to the terms of the Cyprium PPS, shareholders on each record date are entitled to receive a monthly cash dividend of $0.19531 per share which yields an annual dividend of $2.34375 per share. The Cyprium PPS will automatically be redeemed upon the first (and only the first) bona fide, arm's-length sale of a Priority Review Voucher (a "PRV Sale") issued by the FDA in connection with the approval of CUTX-101, Cyprium's copper histidinate product candidate. Upon the PRV Sale, each share of Cyprium PPS will be automatically redeemed in exchange for a payment equal to twice (2x) the $25.00 liquidation preference, plus accumulated and unpaid dividends to, but excluding, the redemption date.

If a PRV Sale has not occurred by March 31, 2026 (the "Exchange Date"), the Cyprium PPS will automatically be exchanged for Fortress Series A Preferred Stock or cash, at the discretion of Fortress.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

*Avenue Subscription and Foregiveness Agreement*

On November 13, 2024, the Company entered into a Subscription and Forgiveness Agreement with Avenue, whereby the Company agreed to convert 50% of a total of $0.5 million owed by the Avenue under the MSA into newly issued common stock of Avenue and forgive the remaining 50% of the accrued balance. Therefore, Avenue issued a total of 122,850 shares to the Company based on the closing price of $2.035 on the day prior to the execution of the agreement.

**16. Segment Information**

The Company operates in two reportable segments, Dermatology Product Sales and Pharmaceutical and Biotechnology Product Development. The accounting policies of the Company are consistently applied to all segments. The following tables summarize, for the periods indicated, operating results from continued operations by reportable segment ($ in thousands):

| Three Months Ended September 30, 2024 | Dermatology Products Sales[1] | Pharmaceutical and Biotechnology Product Development | Consolidated |
|---|---|---|---|
| **Net revenue** | $ 14,629 | $ — | $ 14,629 |
| Cost of goods - product revenue | (5,285) | — | (5,285) |
| Research and development | (842) | (8,604) | (9,446) |
| Selling, general and administrative | (11,396) | (10,597) | (21,993) |
| Asset impairment | — | — | — |
| Other income (expense) | 504 | (5,034) | (4,530) |
| Income tax expense | — | (69) | (69) |
| Segment loss | $ (2,390) | (24,304) | $ (26,694) |

Note 1: As reported by Journey, inclusive of expense eliminated in consolidation.

| Nine Months Ended September 30, 2024 | Dermatology Products Sales[1] | Pharmaceutical and Biotechnology Product Development | Consolidated |
|---|---|---|---|
| **Net revenue** | $ 42,514 | $ 41 | $ 42,555 |
| Cost of goods - product revenue | (18,642) | 0 | (18,642) |
| Research and development | (9,639) | (37,302) | (46,941) |
| Selling, general and administrative | (30,144) | (30,723) | (60,867) |
| Asset impairment | — | (2,649) | (2,649) |
| Other expense | (282) | (7,738) | (8,020) |
| Income tax refund | — | 24 | 24 |
| Segment loss | $ (16,193) | $ (78,347) | $ (94,540) |

| Three Months Ended September 30, 2023 | Dermatology Products Sales[1] | Pharmaceutical and Biotechnology Product Development | Consolidated |
|---|---|---|---|
| **Net revenue** | $ 34,539 | $ 213 | $ 34,752 |
| Cost of goods - product revenue | (6,429) | — | (6,429) |
| Research and development | (2,229) | (18,119) | (20,348) |
| Selling, general and administrative | (8,636) | (13,097) | (21,733) |
| Other income (expense) | (361) | 3,536 | 3,175 |
| Income Tax expense | (95) | (46) | (141) |
| Segment income (loss) | $ 16,789 | $ (27,513) | $ (10,724) |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

| Nine Months Ended September 30, 2023 | Dermatology Products Sales[1] | Pharmaceutical and Biotechnology Product Development | Consolidated |
|---|---|---|---|
| **Net revenue** | $ 63,924 | $ 643 | $ 64,567 |
| Cost of goods - product revenue | (20,645) | — | (20,645) |
| Research and development | (6,036) | (85,959) | (91,995) |
| Selling, general and administrative | (34,069) | (37,443) | (71,512) |
| Asset impairment | (3,143) | — | (3,143) |
| Other Income | (1,646) | (654) | (2,300) |
| Income Tax Expense | (95) | (47) | (142) |
| Segment loss | $ (1,710) | $ (123,460) | $ (125,170) |

Note 1: As reported by Journey, inclusive of expense eliminated in consolidation.

The following tables summarize, for the periods indicated, total assets by reportable segment ($ in thousands):

| September 30, 2024 | Dermatology Products Sales | Pharmaceutical and Biotechnology Product Development | Total Assets |
|---|---|---|---|
| Intangible assets, net | $ 17,844 | $ — | $ 17,844 |
| Tangible assets | 46,200 | 63,041 | 109,241 |
| Total segment assets | $ 64,044 | $ 63,041 | $ 127,085 |

| December 31, 2023 | Dermatology Products Sales | Pharmaceutical and Biotechnology Product Development | Total Assets |
|---|---|---|---|
| Intangible assets, net | $ 20,287 | $ — | $ 20,287 |
| Tangible assets | 56,561 | 90,678 | 147,239 |
| Total segment assets | $ 76,848 | $ 90,678 | $ 167,526 |

**17. Revenues from Contracts and Significant Customers**

*Disaggregation of Total Revenue*

Journey has the following actively marketed products, Qbrexza, Accutane, Amzeeq, Zilxi, Exelderm, Luxamend, Targadox, and Ximino (until September 2023). All of Journey's product revenues are recorded in the U.S.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

The table below summarizes the Company's revenue for the periods presented:

| *($ in thousands)* | Three months ended September 30, 2024 | Three months ended September 30, 2023 | Nine Months Ended September 30, 2024 | Nine Months Ended September 30, 2023 |
|---|---|---|---|---|
| Qbrexza | $ 7,583 | $ 5,865 | $ 19,435 | $ 18,038 |
| Accutane | 3,996 | 4,882 | 15,534 | 15,109 |
| Amzeeq | 1,542 | 2,336 | 3,503 | 4,904 |
| Zilxi | 558 | 681 | 1,200 | 1,567 |
| Other / legacy product revenue | 950 | 1,515 | 2,842 | 4,787 |
| Collaboration revenue | — | 182 | — | 546 |
| Revenue – related party | — | 31 | 41 | 97 |
| Other revenue | — | 19,260 | — | 19,519 |
| Total net revenue | $ 14,629 | $ 34,752 | $ 42,555 | $ 64,567 |

*Significant Customers*

For the three and nine-month periods ending September 30, 2024 and 2023, none of Journey's dermatology products customers accounted for more than 10% of its total gross product revenue.

At September 30, 2024, one of Journey's dermatology products customers accounted for more than 10% of its total accounts receivable balance at 12.4%. At December 31, 2023, one of the Company's dermatology products customers accounted for more than 10% of its total accounts receivable balance at 13%.

**18. Income taxes**

The Company and its subsidiaries are subject to US federal and state income taxes. Income tax expense is the total of the current year income tax due or refundable and the change in deferred tax assets and liabilities. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion, or all, of the deferred tax asset will not be realized.

The Company files a consolidated income tax return with subsidiaries for which the Company has an 80% or greater ownership interest. Subsidiaries for which the Company does not have an 80% or more ownership are not included in the Company's consolidated income tax group and file their own separate income tax return. As a result, certain corporate entities included in these financial statements are not able to combine or offset their taxable income or losses with other entities' tax attributes.

Income tax expense for the three and nine months ended September 30, 2024 and 2023 is based on the estimated annual effective tax rate, and includes interest related to unrecognized tax benefits. The Company expects a net deferred tax asset with a full valuation allowance and 0% estimated annual effective tax rate for 2024. For the three and nine months ended September 30, 2024, income tax expense recognized was $0.1 million and a refund of approximately $24,000, respectively, and for the three and nine months ended September 30, 2023, income tax expense recognized was $0.1 million and $0.1 million, respectively.

**19. Subsequent Events**

*Journey*

On November 4, 2024, Journey announced that the FDA approved Emrosi™ (Minocycline Hydrochloride Extended Release Capsules, 40mg) for the treatment of inflammatory lesions of rosacea in adults. Journey is completing the manufacturing of Emrosi for the U.S. market and anticipates initial supply will be available in the late first quarter or early second quarter of 2025.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Notes to Unaudited Condensed Consolidated Financial Statements**

The approval of Emrosi is supported by positive data from Journey's two Phase 3 clinical trials for the treatment of rosacea. The Phase 3 clinical trials met all co-primary and secondary endpoints, and subjects completed the 16-week treatment with no significant safety issues. Emrosi demonstrated statistically significant superiority over both the current standard-of-care treatment, Oracea® 40mg capsules, and placebo for Investigator's Global Assessment treatment success as well as the reduction in total inflammatory lesion count in both studies.

The approval of Emrosi by the FDA triggered Journey's requirement to draw on the remaining $5.0 million under the Credit Facility with SWK. The FDA approval also triggered a $15.0 million milestone payment obligation to DRL that is due 30 days after the FDA approval.

*Checkpoint*

On November 12, 2024, Checkpoint received approximately $9.2 million from the exercise of existing Series B warrants for the issuance of 3,256,269 shares of common stock from a May 2023 registered direct offering with an exercise price of $2.821 per share.

*Mustang Warrant Inducement and Private Placement*

In October 2024, Mustang entered into a definitive agreement for the exercise of certain existing warrants to purchase an aggregate of 16,877,638 shares of its common stock having an exercise price of $0.237 per share, originally issued in May 2024. The issuance or resale of the shares of common stock issuable upon exercise of the existing warrants are registered pursuant to an effective registration statement filed by Mustang on Form S-1 (File No. 333-278006). The gross proceeds to Mustang from the exercise of the existing warrants are expected to be approximately $4 million, prior to deducting placement agent fees and offering expenses payable by Mustang.

In consideration for the immediate exercise of the existing warrants for cash, Mustang issued two new series of unregistered warrants to purchase up to an aggregate of 33,755,276 shares of common stock. The new warrants will have an exercise price of $0.27 per share and will be exercisable commencing on the effective date of stockholder approval of the issuance of the shares issuable upon exercise of the new warrants (the "Stockholder Approval"). One of the new warrants to purchase 16,877,638 shares of common stock will have a term of five years from the Stockholder Approval, and the other new series of warrants to purchase 16,877,638 shares of common stock will have a term of twelve months from the Stockholder Approval.

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

### Forward-Looking Statements

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. Statements in this Quarterly Report on Form 10-Q that are not descriptions of historical facts are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). The words "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology are generally intended to identify forward-looking statements. These forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include those set forth under "Item 1A. Risk Factors" including, in particular, risks relating to:*

- our growth strategy;
- financing and strategic agreements and relationships;
- our need for substantial additional funds and uncertainties relating to financings;
- our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis;
- our ability to attract, integrate and retain key personnel;
- the early stage of products under development;
- the results of research and development activities;
- uncertainties relating to preclinical and clinical testing;
- the ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates;
- government regulation;
- patent and intellectual property matters; and
- competition.

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this Quarterly Report on Form 10-Q should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

### Overview

Fortress Biotech, Inc. ("Fortress" or the "Company") is a biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holding and dividend and royalty revenue streams. Fortress works in concert with its extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. The Company has executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center ("COH" or "City of Hope"), Fred Hutchinson Cancer Center, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and finance expertise to help the partners achieve their goals. Partner and subsidiary companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, sales transactions, and public and private financings. To date, four partner companies are publicly-traded, and three subsidiaries have consummated strategic partnerships with industry leaders, including AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl").

Our subsidiaries and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are: Avenue Therapeutics, Inc. (Nasdaq: ATXI, "Avenue"), Baergic Bio, Inc. ("Baergic," a subsidiary of Avenue), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, "Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation (Nasdaq: DERM, "Journey" or "JMC"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang") and Oncogenuity, Inc. ("Oncogenuity").

**Recent Events**

***Revenue***

- For the three months ended September 30, 2024 and 2023, total net revenue was $14.6 million and $34.8 million, respectively; and for the nine months ended September 30, 2024 and 2023, was $42.6 million and $64.6 million, respectively, and is comprised predominantly of net product revenue from Journey's commercial dermatology portfolio. For the three and nine months ended September 30, 2023, total net revenue includes a one-time $19.0 million payment from Maruho for a license to additional territories in Asia. Journey, our partner company, primarily focuses on selling and marketing of prescription dermatology products.
- For the three months ended September 30, 2024 and 2023, $14.6 million and $15.3 million, respectively, of net revenue is related to the sale of Journey's branded and generic products. For the nine months ended September 30, 2024 and 2023, $42.5 million and $44.4 million, respectively, of net revenue is related to the sale of Journey's branded and generic products.

***Late Stage Product Candidates***

***Cosibelimab (anti-PD-L1 antibody)***

- Cosibelimab's Biologics License Application ("BLA") is currently under review by the U.S. Food and Drug Administration ("FDA") and has a Prescription Drug User Fee Act ("PDUFA") goal date of December 28, 2024.
- In September 2024, our partner company, Checkpoint presented longer-term data from our pivotal trial of cosibelimab, its investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation in locally advanced and metastatic cSCC, during the European Society for Medical Oncology ("ESMO") Congress 2024. Longer-term results for cosibelimab presented at the ESMO Congress demonstrate a deepening of response over time, with higher objective response and complete response rates than initially observed at the primary analyses.
- In July 2024, Checkpoint, announced the FDA had accepted for review its resubmission of its BLA for cosibelimab,. The resubmission has been accepted as a complete response to the complete response letter received in December 2023, and the FDA has set a PDUFA goal date of December 28, 2024.
- Also in July 2024, Checkpoint announced a collaboration to explore the combined therapeutic potential of cosibelimab with GC Cell's Immuncell-LC, an innovative autologous Cytokine Induced Killer ("CIK") T cell therapy composed of cytotoxic T lymphocytes and natural killer T cells.
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

***Emrosi* (*Minocycline Hydrochloride Extended-Release Capsules, 40mg, also known as DFD-29, for the treatment of rosacea)***

- In November 2024, Journey announced that the FDA approved Emrosi™ (Minocycline Hydrochloride Extended-Release Capsules, 40mg) for the treatment of inflammatory lesions of rosacea in adults. Journey is completing the manufacturing of Emrosi for the U.S. market and anticipates initial supply will be available in the late first quarter or early second quarter of 2025.
- The approval of Emrosi is supported by positive data from Journey's two Phase 3 clinical trials for the treatment of rosacea. The Phase 3 clinical trials met all co-primary and secondary endpoints, and subjects completed the 16-week treatment with no significant safety issues. Emrosi demonstrated statistically significant superiority over both the current standard-of-care treatment, Oracea® 40mg capsules, and placebo for Investigator's Global Assessment treatment success as well as the reduction in total inflammatory lesion count in both studies.
- In October 2024, data assessing the dermal and systemic pharmacokinetics "(PK") of oral DFD-29 (versus oral doxycycline 40 mg capsules (Oracea®) in healthy subjects were presented at the 44th Fall Clinical Dermatology Conference. DFD-29 40mg showed higher dermal concentration than doxycycline from Day 1 onward at a similar dose, which may translate into a clinically meaningful impact for treating patients with rosacea.
- In March 2024, the FDA accepted the NDA for DFD-29 and set a PDUFA goal date of November 4, 2024.
- Emrosi (DFD-29) was developed for the treatment of rosacea at our partner company, Journey, in collaboration with Dr. Reddy's Laboratories Ltd.

***Triplex (cytomegalovirus vaccine)***

- Triplex, a vaccine for control of cytomegalovirus ("CMV"), is currently being studied in a Phase 2 clinical trial for adults co-infected with HIV and CMV that is now fully enrolled with topline data anticipated in the fourth quarter of 2024. The study aims to show that vaccination with Triplex can safely elicit a CMV-specific immune response and reduce asymptomatic CMV replication in a population of people with HIV on suppressive antiretroviral therapy. The study will also evaluate whether this intervention might reduce chronic inflammation and immune activation, as compared to placebo, and thus, potentially reduce related mortality and morbidity.
- In May 2024, we announced that the first patient was dosed in a multi-center, placebo-controlled, randomized Phase 2 study of Triplex in patients undergoing liver transplantation. The trial is funded by a grant from the National Institutes of Health's National Institute of Allergy and Infectious Diseases ("NIH/NIAID") that could provide over $20 million in non-dilutive funding and will be conducted in up to 20 nationally recognized transplant centers in the United States.
- Triplex is currently the subject of multiple ongoing clinical trials, including: a Phase 2 evaluation for CMV control in recipients of liver transplant (NCT06075745); a Phase 1/2 trial for CMV control in pediatric recipients of HCT (NCT03354728); a Phase 2 trial for safety and immunogenicity in adults living with HIV and CMV (NCT05099965); a Phase 2 trial for CMV control in recipients of stem cell transplant in which the stem cell donor is vaccinated with Triplex (NCT06059391) and a Phase 1 trial of Triplex in combination with a bi-specific CMV/CD19 Chimeric Antigen Receptor T Cell for the treatment of non-Hodgkin lymphoma (NCT05432635).
- In 2023, Helocyte additionally entered into an option agreement with City of Hope for exclusive worldwide rights to a novel bispecific CMV/HIV CAR T cell therapy (optionally for use in combination with Triplex), which is currently the subject of a Phase 1 trial in adults living with HIV-1 (see NCT06252402).
- Triplex was sourced by Fortress and is currently in development at our subsidiary, Helocyte.

***CAEL-101 (Light chain fibril-reactive monoclonal antibody for AL Amyloidosis)***

- On October 5, 2021, AstraZeneca acquired Caelum Biosciences, Inc. ("Caelum"), a former subsidiary of Fortress for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $295 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all potential milestone payments, which together with the upfront payment, would total up to approximately $182 million.
- There are two ongoing global Phase 3 studies of CAEL-101 for Mayo Stage IIIa and May Stage IIIb AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).
- CAEL-101 (anselamimab) was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

***CUTX-101 (copper histidinate for Menkes disease)***

- In December 2023, our subsidiary, Cyprium, completed the asset transfer of CUTX-101 (copper histidinate for Menkes disease) to Sentynl, a wholly owned subsidiary of Zydus Lifesciences Ltd. Sentynl is obligated under the agreement to use commercially reasonable efforts to develop and commercialize CUTX-101, including the funding of the same. Additionally, Cyprium remains eligible to receive up to $129 million in aggregate development and sales milestones under the Agreement and royalties on net sales of CUTX-101 ranging from 3% to 12.5% on tiered annual net sales. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at the New Drug Application ("NDA") approval for CUTX-101.
- The rolling NDA for CUTX-101 was completed by Sentynl in the fourth quarter of 2024.
- CUTX-101 was sourced by Fortress and was developed by Cyprium until the asset transfer in December 2023.

***Early Stage Product Candidates***

***MB-106 (CD20-targeted CAR T-cell therapy)***

- In March 2024, we announced our expansion into autoimmune diseases with MB-106, a personalized CD20-targeted, 3rd-generation autologous CAR T-cell therapy. Planning for a proof-of concept Phase 1 investigator-sponsored clinical trial evaluating MB-106 in autoimmune diseases is underway.
- In June 2024, we announced updated data for MB-106 showed a favorable safety and efficacy profile in patients with Waldenstrom macroglobulinemia ("WM"), a rare form of blood cancer. There was an overall response rate ("ORR") of 90% in the cohort with durable responses observed, including three complete responses ("CR"), two very good partial responses ("VGPR"), and four partial responses, and one patient remains in complete remission at 31 months.
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang.

***Dotinurad (urate transporter (URAT1) inhibitor for gout)***

- In July 2024, Urica entered into an asset purchase agreement, royalty agreement, and related agreements (collectively, the "Transaction Documents") with Crystalys Therapeutics, Inc. ("Crystalys"). Crystalys is a Delaware corporation founded in 2023 and seeded by leading life sciences institutional investors. Urica transferred rights to its URAT1 inhibitor product candidate in development for the treatment of gout, dotinurad, and related intellectual property, licenses and agreements to Crystalys. In return, Crystalys issued to Urica shares of its common stock equal to 35% of Crystalys' outstanding equity including certain anti-dilution provisions through the raise of $150 million in equity securities. The Transaction Documents also granted Urica a securitized three percent (3%) royalty on future net sales of dotinurad to be paid by Crystalys, and receive nominal cash reimbursement payments for certain clinical and development costs incurred by Urica related to dotinurad.
- Dotinurad was approved in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials.
- Dotinurad was sourced by Fortress and was in development at Urica until dotinurad was acquired by Crystalys in July 2024.

***MB-109 (IL13Rα2-targeted CAR T Cells (MB-101) + HSV-1 oncolytic virus (MB-108))***

- In November 2024, we announced that the FDA granted Orphan Drug Designation for Mustang for MB-108, a herpes simplex virus type 1 ("HSV-1") oncolytic virus, for the treatment of malignant glioma.
- In March 2024, data from the Phase 1 trial evaluating MB-101 IL13Rα2-targeted CAR T-cells in high-grade glioma were published in *Nature Medicine*. MB-101 was well tolerated and 50% of patients achieved stable disease or better, with two partial responses and two complete responses in high grade glioma patients. The two patients who achieved complete response both had high levels of intratumoral CD3+ T-cells pre-therapy (i.e., "hot" tumors), and their responses lasted 7.5 and 66+ months, respectively. In the cohort with dual intratumoral (ICT) / intraventricular (ICV) delivery and an optimized manufacturing process there was a ~70% improvement in median overall survival (10.2 months) compared to the expected survival rate of six months in this patient population.
- MB-101, MB-108, and MB-109 are currently in development at our partner company, Mustang.

***AJ201 (Nrf1 and Nrf2 activator, androgen receptor degradation enhancer)***

- In May 2024, we announced that last patient completed dosing in a Phase 1b/2a study, which is evaluating AJ201 in the U.S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's Disease. Kennedy's Disease is a debilitating rare genetic neuromuscular disease primarily affecting men. Topline data for the Phase 1b/2a clinical trial of AJ201 in SBMA are expected around year-end 2024.
- AJ201 was sourced by Fortress and is currently in development at our partner company, Avenue.

***General Corporate***

- In July 2024, Checkpoint raised gross proceeds of $12 million in a registered direct offering priced at the-the-market under Nasdaq rules.
- In July 2024, Fortress' Board of Directors paused the payment of dividends on the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock") until further notice. The Company believes pausing the dividend is in the best interest of the Company and its stakeholders to maintain financial flexibility ahead of potentially significant inflection points. The pausing of these dividends will defer approximately $0.7 million in cash dividend payments each month. The Board intends to revisit its decision regarding the monthly dividend regularly and will assess the profitability and cash flow of the Company to determine whether and when the suspension should be lifted.
- Also in July 2024, Journey Medical entered into an amendment of its existing credit facility with SWK, increasing the amount of the facility from $20 million to $25 million.
- Additionally in July 2024, Fortress announced the reduction of total debt outstanding and the entry into a new $50 million term loan with Oaktree Capital Management with a maturity in 2027. The Company borrowed $35.0 million under the agreement on the closing date and is eligible to draw up to an additional $15.0 million at the lenders' discretion to support future business development activities. In connection with the new term loan, Fortress repaid the prior $50 million term loan with Oaktree.
- In September 2024, Fortress raised gross proceeds of $8 million in a registered direct offering and concurrent private placements.
- In October 2024, Mustang raised $4 million in a warrant exercise and concurrent private placement.
- In November 2024, Checkpoint raised $9.2 million in a warrant exercise.

**Critical Accounting Policies and Use of Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. Applying these principles requires our judgment in determining the appropriateness of acceptable accounting principles and methods of application in diverse and complex economic activities. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of revenues, expenses, assets and liabilities, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting estimates, see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 28, 2024 (the "2023 Form 10-K"). There were no material changes in our critical accounting estimates or accounting policies from December 31, 2023.

**Accounting Pronouncements**

See Note 2, "Summary of Significant Accounting Policies", to our unaudited condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

**Smaller Reporting Company Status**

We are a "smaller reporting company," meaning that either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. As a smaller reporting company, we chose to present only the two most recent fiscal years of audited financial statements in the 2023 Form 10-K, have reduced disclosure obligations regarding executive compensation and certain other matters.

**Basis of Presentation and Principles of Consolidation**

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company's consolidated financial statements include the results of the Company's subsidiaries for which it has voting control but does not own 100% of the outstanding equity of the subsidiaries. For consolidated entities where the Company owns less than 100% of the subsidiary, but retains voting control, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations and presents non-controlling interests as a component of stockholders' equity on its consolidated balance sheets. All intercompany income and/or expense items are eliminated entirely in consolidation prior to the allocation of net gain/loss attributable to non-controlling interest, which is based on ownership interests as calculated quarterly for each subsidiary.

The following table summarizes the Company's ownership of the issued and outstanding common and preferred shares in certain consolidated Fortress subsidiaries as of the period presented:

| Partner Company/Subsidiary | September 30, 2024 |
|---|---|
| Avenue[1] | 4.2 % |
| Cellvation | 79.2 % |
| Checkpoint[1] | 9.7 % |
| Cyprium | 75.0 % |
| Helocyte | 83.0 % |
| Journey[1] | 47.6 % |
| Mustang[1] | 7.4 % |
| Oncogenuity | 73.5 % |
| Urica | 68.4 % |

Note 1: Denotes entities that are publicly-traded.

**Results of Operations**

***Comparison of Three Months Ended September 30, 2024 and 2023***

| *($ in thousands)* | Three Months Ended September 30, 2024 | 2023 | Change $ | Change % |
|---|---|---|---|---|
| **Revenue** | | | | |
| Product revenue, net | $ 14,629 | $ 15,279 | $ (650) | (4)% |
| Collaboration revenue | — | 182 | (182) | (100)% |
| Revenue – related party | — | 31 | (31) | (100)% |
| Other revenue | — | 19,260 | (19,260) | (100)% |
| Net revenue | 14,629 | 34,752 | (20,123) | (58)% |
| | | | | |
| **Operating expenses** | | | | |
| Cost of goods sold – product revenue | 5,285 | 6,429 | (1,144) | (18)% |
| Research and development | 9,446 | 20,288 | (10,842) | (53)% |
| Research and development – licenses acquired | — | 60 | (60) | (100)% |
| Selling, general and administrative | 21,993 | 21,733 | 260 | 1 % |
| Total operating expenses | 36,724 | 48,510 | (11,786) | (24)% |
| Loss from operations | (22,095) | (13,758) | (8,337) | 61 % |
| | | | | |
| Other income (expense) | | | | |
| Interest income | 589 | 547 | 42 | 8 % |
| Interest expense and financing fee | (6,209) | (2,534) | (3,675) | 145 % |
| Gain on common stock warrant liabilities | 19 | 4,542 | (4,523) | (100)% |
| Other income | 1,071 | 620 | 451 | 73 % |
| Total other income (expense) | (4,530) | 3,175 | (7,705) | (243)% |
| Loss before income tax expense | (26,625) | (10,583) | (16,042) | 152 % |
| | | | | |
| Income tax expense | 69 | 141 | (72) | (51)% |
| **Net Loss** | **(26,694)** | **(10,724)** | **(15,970)** | **149 %** |
| | | | | |
| Less: net loss attributable to non-controlling interest | 13,827 | 5,679 | 8,148 | 143 % |
| **Net loss attributable to Fortress** | **$ (12,867)** | **$ (5,045)** | **$ (7,822)** | **155 %** |

***Revenue***

| *($ in thousands)* | Three Months Ended September 30, 2024 | 2023 | Change $ | Change % |
|---|---|---|---|---|
| **Revenue** | | | | |
| Product revenue, net | $ 14,629 | $ 15,279 | $ (650) | (4)% |
| Collaboration revenue | — | 182 | (182) | (100)% |
| Revenue – related party | — | 31 | (31) | (100)% |
| Other revenue | — | 19,260 | (19,260) | (100)% |
| **Net revenue** | **$ 14,629** | **$ 34,752** | **$ (20,123)** | **(58)%** |

For the three months ended September 30, 2024 we generated $14.6 million of net revenue related to the sale of Journey's branded and generic products. For the three months ended September 30, 2023, we generated $34.8 million of net revenue, of which $15.3 million relates to the sale of Journey's branded and generic products, $0.2 million relates to Cyprium's collaboration revenue with Sentynl, and other revenue of approximately $19.3 million, which includes Journey's receipt of royalties from its exclusive out-licensing partner for Qbrexza in Japan, Maruho, as well as a $19 million non-refundable upfront payment from Maruho related to a license granted by Journey to Maruho for the development and commercialization of Qbrexza in additional territories in Asia. Since October 2023, Journey has no longer been eligible to receive royalties from Maruho.

For the quarter ended September 30, 2024, the net decrease in revenue of $20.1 million, or 58%, is mainly due to Journey's one-time $19 million up-front payment received in the third quarter of 2023 related to Qbrexza territory licensing. Journey's $0.7 million, or 4%, decrease in product revenue is due primarily to a $0.6 million decrease in net product revenue from legacy products. Qbrexza net product revenue increased by $1.7 million, or 29%, to $7.6 million for the three-month period ended September 30, 2024, from $5.9 million for the three-month period ended September 30, 2023, with the increase primarily driven by additional volume, due to Journey's continued marketing efforts and the recent expansion of access and coverage platforms related to Qbrexza. This revenue increase was offset by a decrease in Accutane revenue of $0.9 million, or 18%, and a combined decrease in Amzeeq and Zilxi of $0.9 million, or 30%. Accutane's decrease is attributed to recent market competition, and Amzeeq and Zilxi revenue is down due to a slight decrease in unit sales volume and an increase in coupon rebates as a result of the expansion of Journey's patient coverage options under its overall market access program driving average selling prices lower as compared to the prior year quarter.

Collaboration revenue related to Cyprium's agreement with Sentynl was fully recognized as of December 31, 2023 due to Sentynl's assumption of control of the CUTX-101 development program in December 2023.

***Cost of Goods Sold***

| *($ in thousands)* | Three Months Ended September 30, 2024 | 2023 | Change $ | Change % |
|---|---|---|---|---|
| Cost of goods sold – product revenue | $ 5,285 | $ 6,429 | $ (1,144) | (18)% |

We incurred $5.3 million and $6.4 million of costs of goods sold in connection with the sale of JMC branded and generic products for the quarters ended September 30, 2024 and 2023, respectively. Cost of goods sold decreased by $1.1 million, or 18% quarter-over-quarter, with the decrease mainly due to $0.6 million in inventory charges recorded in the prior year period and a decrease of $0.2 million in product royalties from the same period in 2023, resulting from lower sales of Accutane and the contractual expiration of the Exelderm product royalty in November 2023.

***Research and Development Expenses***

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

For the quarters ended September 30, 2024 and 2023, research and development expenses were approximately $9.4 million and $20.3 million, respectively. The table below provides a summary of research and development by entity, for the periods presented:

| ($ in thousands) | Three Months Ended September 30, 2024 | 2023 | Change $ | Change % |
|---|---|---|---|---|
| Research & development | | | | |
| Fortress | $ 452 | $ 515 | $ (63) | (12)% |
| Subsidiaries/Partner Companies: | | | | |
| Avenue | 2,264 | 831 | 1,433 | 172 % |
| Checkpoint | 6,366 | 5,495 | 871 | 16 % |
| JMC | 842 | 2,229 | (1,387) | (62)% |
| Mustang | (6) | 9,424 | (9,430) | (100)% |
| Other[1] | (472) | 1,794 | (2,266) | (126)% |
| Total research & development expense | **$ 9,446** | **$ 20,288** | **$ (10,842)** | **(53)%** |

Note 1: Includes the following subsidiaries: Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The decrease in research and development spending at Mustang of $9.4 million is primarily attributed to decreased expenses of $1.6 million for personnel related costs, primarily driven by the reduction in workforce, a decrease of $1.5 million of expense incurred for uBriGene services, a $1.5 million decrease in vector costs, a $2.5 million decrease in lab supplies, a $1.0 million decrease in program related expenses and a $0.9 million decrease in consulting expenses. The decrease in Other of $2.3 million is due to a decrease in clinical costs at Urica of $1.8 million related to the Phase 1b trial and the sale of the asset to Crystalys, and a decrease in research and development costs of $1.0 million at Cyprium due to the asset transfer of CUTX-101 to Sentynl in 2023, offset by an increase of $0.4 million in license costs at both Helocyte and Cellvation. Journey's decrease of $1.4 million is primarily driven by lower clinical trial expenses to develop Emrosi. Avenue's increase in research and development expense of $1.5 million in the quarter ended September 30, 2024 is primarily attributable to an increase in clinical development costs related to AJ201. Checkpoint's increased research and development expense of $0.9 million is due to increased commercial manufacturing costs for cosibelimab of $1.1 million due to manufacturing costs incurred to build inventory to support a potential product launch, partially offset by a $0.5 million decrease in clinical costs for product candidates.

The table below provides a summary by entity of noncash, stock-based compensation expense included in research and development expense for the periods presented:

| ($ in thousands) | Three Months Ended September 30, 2024 | 2023 | Change $ | Change % |
|---|---|---|---|---|
| Stock-based compensation - research & development | | | | |
| Fortress | $ 444 | $ 401 | $ 43 | 11 % |
| Subsidiaries/Partner Companies: | | | | |
| Avenue | 89 | 144 | (55) | (38)% |
| Checkpoint | 543 | 303 | 240 | 79 % |
| JMC | 150 | 24 | 126 | 525 % |
| Mustang | (10) | (18) | 8 | (44)% |
| Other[1] | — | 1 | (1) | (100)% |
| Total stock-based compensation expense - research and development | 1,216 | 855 | 361 | 42 % |

Note 1: Includes the following subsidiaries: Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist principally of personnel related costs, costs required to support the marketing and sales of our commercialized products, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development expenses. For the three months ended September 30, 2024 and 2023, selling, general and administrative expenses were $22.0 million and $21.7 million, respectively. The table below provides a summary by entity of selling, general and administrative expenses for the periods presented:

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Selling, general & administrative | | | | |
| Fortress | $ 4,712 | $ 6,066 | $ (1,354) | (22)% |
| Subsidiaries/Partner Companies: | | | | |
| Avenue | 753 | 1,079 | (326) | (30)% |
| Checkpoint | 2,914 | 1,861 | 1,053 | 57 % |
| JMC | 11,396 | 8,636 | 2,760 | 32 % |
| Mustang | 1,309 | 2,056 | (747) | (36)% |
| Other[1] | 909 | 2,035 | (1,126) | (55)% |
| Total selling, general & administrative expense | **$ 21,993** | **$ 21,733** | **$ 260** | **1 %** |

Note 1: Includes the following subsidiaries: Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the three months ended September 30, 2024, the increase in selling, general and administrative expenses of $0.3 million, or 1%, is primarily attributable to an increase of $2.8 million at Journey due to increased selling and marketing expenses as it prepares for the Emrosi launch, and an increase of $1.1 million at Checkpoint due to an increase in stock-based compensation of $0.7 million due to new employee grants, and an increase in professional fees of $0.4 million. The decrease of $1.4 million at Fortress is related to cost-reduction and optimization efforts, and the decrease in "Other" is primarily attributable to a reduction in general and administrative expenses at Cyprium of $1.2 million. The decrease at Mustang of $0.7 million is due to the workforce reduction that took place in April 2024.

The table below provides a summary by entity of noncash, stock-based compensation expense included in selling, general and administrative expense for the periods presented.

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Stock-based compensation - Selling, general and administrative | | | | |
| Fortress | $ 2,217 | $ 2,061 | $ 156 | 8 % |
| Subsidiaries/Partner Companies: | | | | |
| Avenue | 242 | 417 | (175) | (42)% |
| Checkpoint | 1,067 | 386 | 681 | 176 % |
| JMC | 1,490 | 534 | 956 | 179 % |
| Mustang | 52 | 118 | (66) | (56)% |
| Other[1] | 289 | 6 | 283 | 4717 % |
| Total stock-based compensation expense - selling, general and administrative | 5,357 | 3,522 | 1,835 | 52 % |

Note 1: Includes the following subsidiaries: Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

***Other income (expense)***

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Other income (expense) | | | | |
| Interest income | $ 589 | $ 547 | $ 42 | 8 % |
| Interest expense and financing fee | (6,209) | (2,534) | (3,675) | 145 % |
| Gain on common stock warrant liabilities | 19 | 4,542 | (4,523) | (100)% |
| Other income | 1,071 | 620 | 451 | 73 % |
| Total other income (expense) | $ (4,530) | 3,175 | $ (7,705) | (243)% |

Total other income (expense) decreased $7.7 million, or 243%, from income of $3.2 million for the quarter ended September 30, 2023 to expense of $4.5 million for the quarter ended September 30, 2024, primarily due to the increase of $3.7 million in interest expense and financing fees related to the Oaktree debt paid off by Fortress in 2024 resulting in a loss on extinguishment of debt of $3.6 million, and the $4.5 million increase in the gain on a decrease in fair value of the warrant liabilities, comprised of warrants issued by Checkpoint and Avenue.

***Comparison of Nine Months Ended September 30, 2024 and 2023***

| *($ in thousands)* | Nine Months Ended September 30, 2024 | 2023 | Change $ | Change % |
|---|---|---|---|---|
| **Revenue** | | | | |
| Product revenue, net | $ 42,514 | $ 44,405 | $ (1,891) | (4)% |
| Collaboration revenue | — | 546 | (546) | (100)% |
| Revenue – related party | 41 | 97 | (56) | (58)% |
| Other revenue | — | 19,519 | (19,519) | (100)% |
| Net revenue | 42,555 | 64,567 | (22,012) | (34)% |
| | | | | |
| **Operating expenses** | | | | |
| Cost of goods sold – product revenue | 18,642 | 20,645 | (2,003) | (10)% |
| Research and development | 46,941 | 87,702 | (40,761) | (46)% |
| Research and development – licenses acquired | — | 4,293 | (4,293) | (100)% |
| Selling, general and administrative | 60,867 | 71,512 | (10,645) | (15)% |
| Asset impairment | 2,649 | 3,143 | (494) | (16)% |
| Total operating expenses | 129,099 | 187,295 | (58,196) | (31)% |
| Loss from operations | (86,544) | (122,728) | 36,184 | (29)% |
| | | | | |
| Other income (expense) | | | | |
| Interest income | 2,157 | 2,296 | (139) | (6)% |
| Interest expense and financing fee | (10,933) | (13,255) | 2,322 | (18)% |
| Gain (loss) on common stock warrant liabilities | (578) | 10,708 | (11,286) | (105)% |
| Other income (expense) | 1,334 | (2,049) | 3,383 | (165)% |
| Total other expense | (8,020) | (2,300) | (5,720) | 249 % |
| Loss before income tax expense | (94,564) | (125,028) | 30,464 | (24)% |
| | | | | |
| Income tax expense (refund) | (24) | 142 | (166) | (117)% |
| **Net loss** | **(94,540)** | **(125,170)** | **30,630** | **(24)%** |
| | | | | |
| Less: net loss attributable to non-controlling interest | 55,308 | 73,812 | (18,504) | (25)% |
| **Net loss attributable to Fortress** | **$ (39,232)** | **$ (51,358)** | **$ 12,126** | **(24)%** |

***Revenue***

| *($ in thousands)* | Nine Months Ended September 30, 2024 | 2023 | Change $ | Change % |
|---|---|---|---|---|
| **Revenue** | | | | |
| Product revenue, net | $ 42,514 | $ 44,405 | $ (1,891) | (4)% |
| Collaboration revenue | — | 546 | (546) | (100)% |
| Revenue – related party | 41 | 97 | (56) | (58)% |
| Other revenue | — | 19,519 | (19,519) | (100)% |
| **Net revenue** | **$ 42,555** | **64,567** | **$ (22,012)** | **(34)%** |

For the nine months ended September 30, 2024 we generated $42.6 million of net revenue, the majority of which is related to the sale of Journey's branded and generic products. For the nine months ended September 30, 2023, we generated $64.6 million of net revenue, of which $44.4 million relates to the sale of Journey's branded and generic products, and $0.5 million relates to Cyprium's collaboration revenue with Sentynl, $0.5 relates to Journey's royalties from Maruho and $19 million is the non-refundable upfront payment from Maruho related to a license granted by Journey to Maruho for the development and commercialization of Qbrexza in additional territories in Asia. Since October 2023, Journey has no longer been eligible to receive royalties from Maruho.

The net decrease in revenue of $22.0 million or 34% is mainly due to Journey's one-time $19 million payment received from Maruho related to territory licensing for Qbrexza in the nine months ended September 30, 2023. Net revenue from Journey's legacy products decreased by $1.9 million, or 41%, to $2.8 million for the nine-month period ended September 30, 2024, from $4.8 million for the nine-month period ended September 30, 2023 due to the continued price erosion of Targadox from generic competition.

***Cost of Goods Sold***

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Cost of goods sold – product revenue | $ 18,642 | $ 20,645 | $ (2,003) | (10)% |

Costs of goods sold in connection with the sale of JMC branded and generic products for the nine months ended September 30, 2024 and 2023 was $18.6 million and $20.6 million, respectively. The decrease in cost of goods sold of $2.0 million, or 10%, is mainly due to product royalties that were lower by $1.0 million compared to the same period in 2023 due to the contractual expiration of Journey's Exelderm product royalty in November 2023, the contractual decrease in the Qbrexza royalty in the second quarter of 2023, and the discontinuation of Ximino in September of 2023. In addition, the discontinuation of Ximino has resulted in lower PDUFA fees of $0.8 million and lower non-cash license amortization of $0.5 million. These decreases were offset by an increase in product costs of $0.5 million, as a result of product mix, mainly driven by the higher Accutane net product revenue.

***Research and Development Expenses***

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

For the nine months ended September 30, 2024 and 2023, research and development expenses were approximately $47.1 million and $87.7 million, respectively. The table below provides a summary of research and development by entity, for the periods presented:

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Research & development | | | | |
| Fortress | $ 1,395 | $ 1,652 | $ (257) | (16)% |
| Subsidiaries/Partner Companies: | | | | |
| Avenue | 5,892 | 4,781 | 1,111 | 23 % |
| Checkpoint | 19,343 | 35,266 | (15,923) | (45)% |
| JMC | 9,641 | 6,036 | 3,605 | 60 % |
| Mustang | 8,033 | 34,149 | (26,116) | (76)% |
| Other[1] | 2,637 | 5,818 | (3,181) | (55)% |
| Total research & development expense | **$ 46,941** | **$ 87,702** | **$ (40,761)** | **(46)%** |

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The decrease in research and development spending at Mustang of $26.1 million is primarily attributable to a reduction in personnel-related costs of $12.5 million, $7.4 million reduction in lab supplies, $4.2 million decrease in program-related expenses, $1.5 million decrease in facility and depreciation, and $2.0 million reduction in consulting expense, offset by a $1.5 million increase in other expenses, primarily related to approximately $3.2 million of expenses incurred related to the June 2024 Repurchase of Assets from uBriGene. Checkpoint's reduced research and development expense of $15.9 million is due to reduced commercial manufacturing costs for cosibelimab of $9.5 million related to manufacturing costs incurred in the prior period to build inventory to support a potential product launch of cosibelimab, reduced regulatory expenses of $3.5 million as prior period costs included $3.2 million for the PDUFA fee for the BLA filing of cosibelimab in the first quarter of 2023, and a $2.1 million decrease in clinical costs for product candidates. Journey's increased research and development costs of $3.6 million are due to the $4.1 million filing fee payment made to the FDA in January 2024 for the DFD-29 NDA submission in addition to the $3.0 million contractual milestone payment made to Dr. Reddy's Laboratories, Ltd. triggered by the FDA's acceptance of the DFD-29 NDA in March 2024. This increase was partially offset by lower clinical trial expenses incurred by Journey as the clinical program was concluded.

Noncash, stock-based compensation expense included in research and development for the nine months ended September 30, 2024 and 2023, was $2.9 million and $2.3 million, respectively.

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Stock-based compensation - research & development | | | | |
| Fortress | $ 1,319 | $ 1,200 | $ 119 | 10 % |
| Partner Companies: | | | | |
| Avenue | 179 | 150 | 29 | 19 % |
| Checkpoint | 1,629 | 880 | 748 | 85 % |
| JMC | 466 | 88 | 377 | 426 % |
| Mustang | (650) | — | (650) | 100 % |
| Other[1] | — | 1 | (1) | (100)% |
| Total stock-based compensation expense - research and development | $ 2,943 | 2,319 | $ 624 | 27 % |

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

We expect research and development costs to remain lower in 2024 due to portfolio optimization and assets completing pivotal trials in 2023 and entering registration and approval stages.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist principally of personnel related costs, costs required to support the marketing and sales of our commercialized products, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development expenses. For the nine months ended September 30, 2024 and 2023, selling, general and administrative expenses were $60.9 million and $71.5 million, respectively. The table below provides a summary by entity of selling, general and administrative expenses for the periods presented:

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Selling, general & administrative | | | | |
| Fortress | $ 13,978 | $ 17,849 | $ (3,871) | (22)% |
| Subsidiaries/Partner Companies: | | | | |
| Avenue | 3,235 | 2,733 | 502 | 18 % |
| Checkpoint | 6,953 | 5,625 | 1,328 | 24 % |
| JMC | 30,142 | 34,069 | (3,927) | (12)% |
| Mustang | 3,979 | 7,291 | (3,312) | (45)% |
| Other[1] | 2,580 | 3,945 | (1,365) | (35)% |
| Total selling, general & administrative expense | **$ 60,867** | **$ 71,512** | **$ (10,645)** | **(15)%** |

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the nine months ended September 30, 2024, the decrease in selling, general and administrative expenses of $10.6 million, or 15%, is primarily attributable to decreased expenses at Fortress related to cost-reduction and optimization efforts and at Journey related to its expense reduction efforts in sales and marketing, as JMC has undertaken a cost reduction initiative designed to improve operational efficiencies, optimize expenses and reduce overall costs to better align costs to their revenue-generating capabilities. The decrease in selling, general and administrative costs at Mustang is attributable to continued cost reduction efforts and optimization relating to personnel, consulting, and infrastructure. The decrease in Other is led by reduced professional fees and legal spending at Urica and Cyprium. The increase of $1.3 million at Checkpoint is attributable to an increase in stock-based compensation of $0.6 million due to new employee grants, and an increase in professional fees of $0.8 million.

The table below provides a summary by entity of noncash, stock-based compensation expense included in selling, general and administrative expense for the periods presented.

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Stock-based compensation - Selling, general and administrative | | | | |
| Fortress | $ 6,280 | $ 6,787 | $ (507) | (7)% |
| Partner Companies: | | | | |
| Avenue | 535 | 449 | 86 | 19 % |
| Checkpoint | 1,862 | 1,345 | 517 | 38 % |
| JMC | 4,254 | 1,989 | 2,265 | 114 % |
| Mustang | 150 | 380 | (230) | (61)% |
| Other[1] | 407 | 56 | 350 | 621 % |
| Total stock-based compensation expense - selling, general and administrative | $ 13,488 | 11,006 | $ 2,482 | 23 % |

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

We expect selling, general and administrative expenses to remain flat or slightly lower for 2024.

***Asset Impairment***

For the nine months ended September 30, 2024, we incurred impairment charges of $2.6 million attributable to Mustang's assessment of the recoverability of the asset group consisting of its leasehold improvements and the associated right-of-use asset. For the nine months ended September 30, 2023, Journey recorded a loss on the impairment of intangible assets of $3.1 million related to the impairment of the Ximino intangible asset, due to lower net product revenue and gross profit levels for the Ximino products.

***Other Expense***

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | 2024 | 2023 | $ | % |
| Other expense | | | | |
| Interest income | $ 2,157 | $ 2,296 | $ (139) | (6)% |
| Interest expense and financing fee | (10,933) | (13,255) | 2,322 | (18)% |
| Gain (loss) on common stock warrant liabilities | (578) | 10,708 | (11,286) | (105)% |
| Other income (expense) | 1,334 | (2,049) | 3,383 | (165)% |
| Total other expense | $ (8,020) | (2,300) | $ (5,720) | 249 % |

Total other expense increased $5.7 million, or 249%, from expense of $2.3 million for the nine months ended September 30, 2023 to expense of $8.0 million for the nine months ended September 30, 2024, primarily due to the decrease of $11.3 million in the gain on common stock warrant liabilities, offset by the $2.3 million decrease in interest expense and financing fees due to debt paid off by JMC and Mustang in 2023, as well as the $3.4 million increase in other income due in part to Journey's $1.1 million gain on the extinguishment of short-term debt related to installment payments for the license of Ximino. Other expense in the nine months ended September 30, 2023 was comprised of a $4.1 million loss on the deconsolidation of Aevitas, offset by Mustang's gain on the sale of assets to uBriGene of $1.4 million, and grant income of $0.7 million.

**Liquidity and Capital Resources**

We will require additional financing to fully develop and prepare regulatory filings and obtain regulatory approvals for our existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products, and sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt securities. At September 30, 2024, we had cash and cash equivalents of $58.9 million, of which $25.6 million relates to Fortress and private subsidiaries primarily funded by Fortress, $4.7 million relates to Checkpoint, $3.5 million relates to Mustang, $22.5 million relates to Journey, and $2.6 million relates to Avenue. We believe that our current cash and cash equivalents are sufficient to fund operations for at least the next 12 months. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, joint venture or similar development collaborations, the sales of subsidiaries/partner companies, royalty financings, or through other sources of financing; the rising interest rate environment may cause the Company to pay more interest on its various debt instruments, which could lead to higher operating expenses.

***Cash Flows for the Nine Months Ended September 30, 2024 and 2023***

Components of cash flows from publicly-traded partner companies comprise:

| | For the Nine Months Ended September 30, 2024 | | | | | |
|---|---|---|---|---|---|---|
| ***($ in thousands)*** | **Fortress[1]** | **Avenue** | **Checkpoint** | **JMC** | **Mustang** | **Total** |
| Statement of cash flows data: | | | | | | |
| Total cash (used in)/provided by: | | | | | | |
| Operating activities | $ (14,333) | $ (8,262) | $ (23,924) | $ (11,352) | $ (9,413) | $ (67,284) |
| Investing activities | — | — | — | — | — | — |
| Financing activities | (643) | 9,076 | 23,699 | 6,374 | 6,329 | 44,835 |
| Net increase (decrease) in cash and cash equivalents and restricted cash | $ (14,976) | $ 814 | $ (225) | $ (4,978) | $ (3,084) | $ (22,449) |

| | For the Nine Months Ended September 30, 2023 | | | | | |
|---|---|---|---|---|---|---|
| ***($ in thousands)*** | **Fortress[1]** | **Avenue** | **Checkpoint** | **JMC** | **Mustang** | **Total** |
| Statement of cash flows data: | | | | | | |
| Total cash (used in)/provided by: | | | | | | |
| Operating activities | $ (24,943) | $ (7,127) | $ (40,757) | $ 21,760 | $ (42,223) | $ (93,290) |
| Investing activities | 44 | (3,000) | — | (5,000) | 5,916 | (2,040) |
| Financing activities | 9,131 | 3,580 | 30,461 | (24,014) | (30,037) | (10,879) |
| Net decrease in cash and cash equivalents and restricted cash | $ (15,768) | $ (6,547) | $ (10,296) | $ (7,254) | $ (66,344) | $ (106,209) |

Note 1: Includes Fortress, non-public subsidiaries and elimination entries.

Cash flows on a consolidated basis are as follows:

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| ***($ in thousands)*** | **2024** | **2023** | **Change** |
| Total cash (used in)/provided by: | | | |
| Operating activities | $ (67,284) | $ (93,290) | $ 26,006 |
| Investing activities | — | (2,040) | 2,040 |
| Financing activities | 44,835 | (10,879) | 55,714 |
| Net decrease in cash and cash equivalents and restricted cash | $ (22,449) | $ (106,209) | $ 83,760 |

***Operating Activities***

Net cash used in operating activities decreased $26.0 million from the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2024. The decrease is due to the decrease of $30.6 million in net loss, the $11.1 million decrease in the expense associated with subsidiaries/partner companies' warrant liabilities, and the $8.0 million decrease resulting from changes in operating assets and liabilities, offset in part by the $3.1 million change in the expense for research and development – licenses acquired, $4.1 million change in the expense for loss from deconsolidation and dissolution of subsidiaries, and $3.1 million for Journey's asset impairment loss in the prior period.

***Investing Activities***

Net cash used in investing activities for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 is a decrease of $2.0 million, due to JMC's $5.0 million used in investing activities for the deferred cash payment made to VYNE related to the acquisition of Amzeeq and Zilxi and Avenue's $3.0 million cash payment towards the purchase of the AnnJi license, each in the nine months ended September 30, 2023, offset by Mustang's $6.0 million proceeds from the sale of assets to uBriGene in July 2023, and no comparable activities in the period ended September 30, 2024.

***Financing Activities***

Net cash used in financing activities was $10.9 million for the nine months ended September 30, 2023, compared to $44.8 million of net cash provided by financing activities for the nine months ended September 30, 2024, an increase of $55.7 million. The increase is attributable to the funds used in the prior period to pay off partner companies' long-term debt of $50.4 million and JMC's line of credit of $30.9 million, offset by loan proceeds of $38.7 million, proceeds from partner companies' sale of stock, options and warrants of $37.1 million in the current period.

We fund our operations through cash on hand, the sale of equity and debt securities, from the sales of subsidiaries/partner companies, and from the proceeds resulting from the exercise of warrants and stock options. At September 30, 2024, we had cash and cash equivalents of $58.9 million, of which $25.6 million relates to Fortress and private subsidiaries primarily funded by Fortress, $4.7 million relates to Checkpoint, $3.5 million relates to Mustang, $22.5 million relates to Journey, and $2.6 million relates to Avenue. Restricted cash at September 30, 2024 was $2.1 million, of which $1.2 million relates to Fortress, $0.4 million relates to Mustang, and $0.5 million relates to Cyprium.

***Sources of Liquidity***

*Stock Offerings and At-The-Market Share Issuances*

*Fortress*

On May 17, 2024, the Company filed a shelf registration statement (File No. 333-279516) on Form S-3, which was declared effective on May 30, 2024 (the "2024 Shelf"). As of September 30, 2024, $43.5 million of securities were available for sale under the 2024 Shelf, subject to General Instruction I.B.6. of Form S-3, known as the "baby shelf rules," which limit the number of securities that can be sold under registration statements on Form S-3.

During the nine months ended September 30, 2024, the Company issued and sold approximately 1.8 million shares at an average price of $1.95 per share for gross proceeds of $3.5 million under the Company's at-the-market offering program.

In September 2024, Fortress closed a registered direct offering of an aggregate of 3,939,394 shares of its common stock at a purchase price of $1.65 per share. In a concurrent private placement, the Company also agreed to issue to the same investors that participated in the registered direct offering warrants to purchase up to 3,939,394 shares of common stock. The private placement warrants have an exercise price of $1.84 per share, will be exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issue.

In a separate concurrent private placement, Dr. Rosenwald purchased 763,359 shares of common stock at a price of $1.84 per share, which represented the consolidated closing bid price of the common stock on the Nasdaq Capital Market on September 19, 2024, and warrants to purchase up to 763,359 shares of common stock, purchased at a price of $0.125 per warrant. The warrants in the concurrent private placement have an exercise price of $1.84 per share, will be exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issue. Net proceeds to Fortress from the September 2024 registered direct offering and the concurrent private placements, after deducting the placement agent's fees and other offering expenses and assuming no exercises of the warrants issued in the transactions, were approximately $7.4 million.

In January 2024, Fortress closed on a registered direct offering of 3,303,305 shares of its common stock and warrants to purchase up to 3,303,305 shares of its common stock at a combined purchase price of $3.33 per share of common stock and accompanying warrant priced at-the-market under Nasdaq rules. The warrants have an exercise price of $3.21 per share, are immediately exercisable, and will expire five years following the date of issue. Net proceeds to Fortress, after deducting the placement agent's fees and other offering expenses, were approximately $10.2 million.

*Checkpoint*

In March 2023, Checkpoint filed shelf registration statement (File No. 333-270843) on Form S-3 (the "Checkpoint 2023 S-3"), which was declared effective May 5, 2023. Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of September 30, 2024, approximately $65.7 million of the securities remains available for sale through the Checkpoint 2023 S-3.

In July 2024, Checkpoint closed on a registered direct offering (the "Checkpoint July 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,230,000 shares of its common stock at a purchase price of $2.05 per share of common stock. In addition, the offering included 4,623,659 shares of common stock in the form of pre-funded warrants at a price of $2.0499. In a concurrent private placement, Checkpoint issued and sold common warrants (the "Checkpoint July 2024 Common Stock Warrants") to purchase up to 5,853,659 shares of common stock. The Checkpoint July 2024 Common Stock Warrants will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Checkpoint July 2024 Common Stock Warrants with an exercise price of $2.05 per share and will expire five years following the issuance date. Checkpoint also issued the placement agent warrants to purchase up to 351,220 shares of common stock with an exercise price of $2.5625 per share. The total net proceeds from the July 2024 Registered Direct Offering, after deducting placement agent's fees and other offering expenses, were approximately $11.0 million.

In January 2024, Checkpoint closed on a registered direct offering (the "Checkpoint January 2024 Registered Direct Offering") for the issuance and sale of 1,275,000 shares of its common stock and 6,481,233 pre-funded warrants. Each pre-funded warrant was exercisable for one share of Checkpoint common stock. The Checkpoint common stock and the pre-funded warrants were sold together with common stock warrants (the "Checkpoint January 2024 Common Warrants") to purchase up to 7,756,233 shares of Checkpoint common stock, at a purchase price of $1.805 per share of common stock and $1.8049 per pre-funded warrant. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001 and are exercisable commencing on the closing date and will terminate when such pre-funded warrants are exercised in full. The Checkpoint January 2024 Common Warrants are exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of $1.68 per share. Checkpoint also issued the placement agent warrants to purchase up to 465,374 shares of common stock with an exercise price of $2.2563 per share. Net proceeds to Checkpoint from the Checkpoint January 2024 Registered Direct Offering were $12.6 million after deducting commissions and other transaction costs. As of July 2024, all of the pre-funded warrants from the Checkpoint January 2024 Registered Direct Offering were fully exercised.

*Avenue*

In December 2021, Avenue filed a shelf registration statement (File No. 333-261520) on Form S-3 (the "Avenue 2021 S-3"), which was declared effective on December 10, 2021. As of September 30, 2024, approximately $24.1 million of the securities remains available for sale through the Avenue 2021 S-3, subject to General Instruction I.B.6. of Form S-3.

On January 5, 2024, Avenue entered into (i) an inducement offer letter agreement (the "January 2023 Investor Inducement Letter") with a certain investor (the "January 2023 Investor") in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 shares of Common Stock, originally issued to the January 2023 Investor on January 31, 2023 (the "January 2023 Warrants") and (ii) an inducement offer letter agreement (the "November 2023 Investor Inducement Letter Agreement" and, together with the January 2023 Investor Inducement Letter, the "January 2024 Warrant Inducement") with certain investors (the "November 2023 Investors" and, together with the January 2023 Investor, the "Holders") in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of Common Stock, originally issued to the November 2023 Investors on November 2, 2023 (the "November 2023 Warrants" and, together with the January 2023 Warrants, the "Existing Warrants"). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise its January 2023 Warrants for cash at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise their November 2023 Warrants for cash at the existing exercise price of $22.545, in each case in consideration for Avenue's agreement to issue in a private placement (x) Series A Warrants to purchase up to 220,538 shares of Avenue Common Stock and (y) Series B Warrants to purchase up to 220,538 shares of Avenue Common Stock. The net proceeds to Avenue from the exercise of the warrants was approximately $4.5 million, after deducting placement agent fees and estimated offering costs, but without giving effect to the exercise of the Series A Warrants and Series B Warrants issued in the January 2024 Warrant Inducement.

Also in April 2024, Avenue entered into definitive agreements for the immediate exercise of certain of its existing outstanding warrants for cash of an aggregate of 689,680 warrants for shares of Avenue's common stock at a reduced exercise price of $6.20 per share (the "May 2024 Warrant Inducement"). The exercised warrants are comprised of warrants to purchase shares of common stock originally issued by Avenue on October 11, 2022, each having an exercise price of $116.25 per share, Series A and Series B warrants to purchase shares of common stock originally issued by Avenue on November 2, 2023, each having an exercise price of $22.545 per share, and warrants to purchase shares of common stock originally issued by Avenue on January 9, 2024, each having an exercise price of $22.545 per share.

In consideration for the immediate exercise of the warrants for cash in the May 2024 Warrant Inducement, Avenue issued two new unregistered series of warrants to purchase up to a total of 1,379,360 shares of Avenue common stock for a payment of $0.125 per warrant. The warrants have an exercise price of $6.20 per share, and terms of eighteen months for one series and five years for the other series. Total net proceeds to Avenue were approximately $3.7 million after deducting placement agent fees and other expenses payable by Avenue.

In May 2024, Avenue entered into an At-the-Market Offering Agreement (the "Avenue ATM") with H.C. Wainwright & Co. LLC ("Wainwright") under which Avenue may offer and sell, from time to time at its sole discretion, up to $3,850,000 of shares of its common stock, par value $0.0001 per share (the "Shares"), through or to Wainwright. The offer and sale of the Shares will be made pursuant to a base prospectus forming a part of the 2021 Avenue S-3, and the related prospectus supplement dated May 10, 2024. During the nine months ended September 30, 2024, Avenue issued 245,617 shares through the Avenue ATM for net proceeds of $0.9 million.

*Mustang*

On April 23, 2021, Mustang filed a shelf registration statement on Form S-3 (File No. 333-255476) (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Under the Mustang 2021 S-3, Mustang was able to sell up to a total of $200.0 million of its securities. In 2024, Mustang sold approximately $4.4 million of securities under the Mustang 2021 S-3 until Mustang's ability to register new offers and sales of securities under such registration statement expired on May 24, 2024.

On May 31, 2024, Mustang filed a shelf registration statement on Form S-3 (File No. 333-279891) (the "Mustang 2024 S-3"), which was declared effective on June 12, 2024. Under the Mustang 2024 S-3, Mustang may sell up to a total of $40.0 million of its securities. As of September 30, 2024, approximately $36.3 million of the Mustang 2024 S-3 remains available for sales of securities, subject to the General Instruction I.B.6 to Form S-3. The ability of Mustang to register new offers and sales of securities under the Mustang 2024 S-3 expires on June 12, 2027.

On May 31, 2024, Mustang entered into an At-the-Market Offering Agreement (the "Mustang ATM") relating to the sale of shares of common stock pursuant to the Mustang 2024 S-3. Under the Mustang ATM, Mustang pays the sales agents for the program a commission rate of 3.0% of the gross proceeds from the sale of any shares of common stock. During the nine months ended September 30, 2024, Mustang issued approximately 2.7 million shares through the Mustang ATM for net proceeds of approximately $1.2 million.

In May 2024, Mustang closed on an equity offering of 1,160,000 shares of common stock and pre-funded warrants to purchase up to 15,717,638 shares of common stock (or common stock equivalents in lieu thereof), and three series of 50,632,914 warrants with a combined equity offering price of $0.237 per share (or per share common stock equivalent in lieu thereof) and accompanying warrants with an exercise price of $0.237 per share. The Series A-1 warrants have a five-year term, the Series A-2 warrants have a twenty-four month term, and the Series A-3 warrants have a nine month term. The warrants contain customary anti-dilution adjustments to the exercise price, including share splits, share dividends, rights offerings and pro rata distributions. The net proceeds of the equity offering, after deducting the fees and expenses of the placement agent and other offering expenses payable by Mustang, but excluding the net proceeds, if any, from the exercise of the warrants, was approximately $3.2 million. All of the 15,717,638 pre-funded warrants have since been exercised.

In June 2024, Mustang closed on a registered direct offering of 3,025,000 shares of common stock at $0.41 per share (or common stock equivalent) priced at-the-market under Nasdaq rules and pre-funded warrants to purchase up to 3,105,000 shares of common stock, at a price per pre-funded warrant equal to $0.4099, the price per share of common stock, less $0.001. The pre-funded warrants have an exercise price of $0.001 per share, became exercisable upon issuance and remain exercisable until exercised in full. In a concurrent private placement, Mustang also agreed to issue and sell unregistered warrants to purchase up to 6,130,000 shares of its common stock, with an exercise price of $0.41 per share, exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the warrants and will expire five years from the date of stockholder approval. Net proceeds were approximately $2.1 million, after placement agent's fees and other offering expenses of approximately $0.3 million. All of the 3,105,000 pre-funded warrants have since been exercised.

*Journey*

On December 30, 2022, Journey filed a shelf registration statement on Form S-3 (File No. 333-269079) (the "Journey 2022 S-3"), which was declared effective on January 26, 2023. The Journey 2022 S-3 covers the offering, issuance and sale by Journey of up to an aggregate of $150.0 million of Journey's common stock, preferred stock, debt securities, warrants, and units. In connection with the Journey 2022 S-3, Journey has entered into the Sales Agreement relating to shares of the Journey's common stock. In accordance with the terms of the Sales Agreement, Journey may offer and sell up to 4,900,000 shares of its common stock, par value $0.0001 per share, from time to time. For the nine months ended September 30, 2024, Journey issued and sold approximately 0.3 million shares of common stock at for gross proceeds of $1.7 million under the Journey ATM. In connection with these sales, Journey paid aggregate fees of approximately $46,000. At September 30, 2024, 3.8 million shares remain available for issuance under the Journey 2022 S-3.

***Contractual Obligations***

We enter into contracts in the normal course of business with licensors, contract research organizations (CROs), contract manufacturing organizations (CMOs) and other third parties for the procurement of various products and services, including without limitation biopharmaceutical development, biologic assay development, commercialization, clinical and preclinical development, clinical trials management, pharmacovigilance and manufacturing and supply. These contracts typically do not contain minimum purchase commitments (although they may) and are generally terminable by us upon written notice. Payments due upon termination or cancelation/delay consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation; in certain cases, our contractual arrangements with CROs and CMOs include cancelation and/or delay fees and penalties.

During the nine months ended September 30, 2024, there were no material changes in our contractual obligations and commitments, including our lease obligations, as described in our 2023 Form 10-K with the exception of the long-term debt. On July 25, 2024, Fortress entered into the $50.0 million senior secured credit agreement with a maturity date of July 25, 2027 with Oaktree Fund Administration, LLC (the "New Oaktree Agreement"). The Company borrowed $35.0 million under the New Oaktree Agreement on the Closing Date (the "2024 Oaktree Note") and is eligible to draw up to an additional $15.0 million at the lenders' discretion to support future business development activities. The 2024 Oaktree Note replaces the previous note made to the Oaktree in 2020, with respect to which the remaining $50.0 million balance on the prior note was repaid in full.

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

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide the information required by this item.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of September 30, 2024, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

*Changes in Internal Control over Financial Reporting*

No change in internal control over financial reporting occurred during the most recent quarter, which materially affected, or is reasonable likely to materially affect, our internal controls over financial reporting.

## PART II. OTHER INFORMATION

**Item 1. Legal Proceedings**

There are no reportable events or material developments with respect to previously disclosed proceedings for the quarter ended September 30, 2024. To our knowledge, except as previously disclosed, there are no legal proceedings pending against us, other than routine actions and administrative proceedings, and other actions not deemed material are not expected to have a material adverse effect on our financial condition, results of operations, or cash flows. In the ordinary course of business, however, the Company may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages.

**Item 1A. Risk Factors**

*Investing in our Common Stock, our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value (the "Series A Preferred Stock") or any other type of equity or debt securities we may issue from time to time (together our "Securities") involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q including the consolidated financial statements and the related notes, as well as the risks, uncertainties and other information set forth in the reports and other materials filed or furnished by our partner companies Avenue, Checkpoint, Journey and Mustang with the SEC, before deciding to invest in our Securities. If any of the following risks or the risks included in the public filings of Avenue, Checkpoint, Journey or Mustang were to materialize, our business, financial condition, results of operations, and future growth prospects could be materially and adversely affected. In that event, the market price of our Securities could decline, and you could lose part of or all of your investment in our Securities. In addition, you should be aware that the below stated risks should be read as being applicable to our subsidiaries and partner companies such that, if any of the negative outcomes associated with any such risk is experienced by one of our subsidiaries or partner companies, the value of Fortress' holdings in such entity may decline. As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually, to one or more subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.*

Risks Inherent in Drug Development

***Most of our product candidates are in the early stages of development and may not be successfully developed or commercialized, and the product candidates that do advance into clinical trials may not receive regulatory approval.***

Most of our existing product candidates remain in the early stages of development and will require substantial further capital expenditures, development, testing and regulatory approvals prior to commercialization. The development and regulatory approval processes can take many years, and it is unlikely that our product candidates, even if successfully developed and approved by the FDA and/or foreign equivalent regulatory bodies, would be commercially available for several years. Only a small percentage of drugs under development successfully obtain regulatory approval and are successfully commercialized. Accordingly, even if we are able to obtain the requisite financing to fund development programs, we cannot be sure that any of our product candidates will be successfully developed or commercialized, which could result in the failure of our business and a loss of your investment.

Pharmaceutical development has inherent risks. Before we may seek regulatory approval for the commercial sale of any of our product candidates, we will be required to demonstrate, through well-controlled clinical trials, that our product candidates are effective and have a favorable benefit-risk profile for their target indications. Success in early clinical trials is not necessarily indicative of success in later stage clinical trials, during which product candidates may fail to demonstrate sufficient safety or efficacy, despite having progressed through initial clinical testing, which may cause significant setbacks. Further, we may need to conduct additional clinical trials that are not currently anticipated. As a result, product candidates that we advance into clinical trials may never receive regulatory approval.

Even if any of our product candidates are approved, regulatory authorities may approve any such product candidates for fewer or more limited indications than we request, may place limitations on our ability to commercialize products at the intended price points, may grant approval contingent on the product's performance in costly post-marketing clinical trials, or may approve a label that does not include the claims necessary or desirable for the successful commercialization of that product candidate. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product. In addition, the Drug Enforcement Agency ("DEA"), or foreign equivalent, may schedule one or more of our product candidates under the Controlled Substances Act, or its foreign equivalent, which could impede such product's commercial viability. Any of these scenarios could impact the commercial prospects for one or more of our current or future product candidates.

***The extensive regulation to which our product candidates are subject may be costly and time consuming, cause anticipated or unanticipated delays, and/or prevent the receipt of the required approvals for commercialization.***

The research and clinical development, testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of any product candidate, including our product candidates, is subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market a product candidate until the FDA approves such product candidate's BLA or NDA. The approval process is uncertain, expensive, often spans many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. In addition to significant and expansive clinical testing requirements, our ability to obtain marketing approval for product candidates depends on the results of required non-clinical testing, including the characterization of the manufactured components of our product candidates and validation of our manufacturing processes.

The FDA may determine that our manufacturing processes, testing procedures or equipment and facilities are inadequate to support approval. Further, the FDA has substantial discretion in the pharmaceutical approval process and may change approval policies or interpretations of regulations at any time, which could delay, limit or preclude a product candidate's approval.

The FDA and other regulatory agencies may delay, limit or refuse approval of a product candidate for many reasons, including, but not limited to:

- disagreement with the trial design or implementation of our clinical trials, including proper use of clinical trial methods and methods of data analysis;
- an inability to establish sufficient data and information to demonstrate that a product candidate is safe and/or effective for an indication;
- the FDA's rejection of clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States;

- the FDA's determination that clinical trial results do not meet the statistical significance levels required for approval;
- a disagreement by the applicable regulator regarding the interpretation of preclinical study or trial data;
- determination by the FDA that our manufacturing processes or facilities or those of third-party manufacturers with which we or our collaborators contract for clinical supplies or plan to contract for commercial supplies, do not satisfactorily comply with cGMPs; or
- a change to the FDA's approval policies or interpretation of regulations rendering our clinical data, product characteristics, or benefit-risk profile insufficient or unfavorable for approval.

Foreign approval procedures vary by country and may, in addition to the aforementioned risks, involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, rapid drug and biological development during the COVID-19 pandemic has raised questions about the safety and efficacy of certain marketed pharmaceuticals and may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals may prevent us from commercializing our product candidates.

***Delays in the commencement of our clinical trials, or suspensions or terminations of such trials, could result in increased costs and/or delay our ability to pursue regulatory approvals.***

The commencement or resumption of clinical trials can be delayed for a variety of reasons, including, but not necessarily limited to, delays in:

- obtaining regulatory approval to commence or resume a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching and maintaining agreements on acceptable terms with CROs and trial sites, the terms of which may be subject to extensive negotiation and modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining IRB or ethics committee approval to conduct a clinical trial at a prospective site;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical sites once a trial has begun;
- the death, disability, departure or other change to the principal investigator or other staff overseeing the clinical trial at a given site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; or
- retaining patients who participate in a clinical trial and replacing those who may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, personal issues, or other reasons.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the termination of a given development program or the denial of regulatory approval of a product candidate.

If any of our product candidates causes unacceptable adverse safety events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product, preventing us from generating revenue from such products' sale. Alternatively, even if a product candidate is approved for marketing, future adverse events could lead to the withdrawal of such product from the market.

***Suspensions or delays in the completion of clinical testing could result in increased costs and/or delay or prevent our ability to complete development of that product candidate or generate product revenues.***

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities, due to a number of factors, including, but not necessarily limited to:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety or chemistry, manufacturing and control issues, or other determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Regulatory requirements and guidance may change, and we may need to amend clinical trial protocols to reflect these changes. Any such change may require us to resubmit clinical trial protocols to IRBs, which may in turn impact a clinical trial's cost, timing, and likelihood of success. If any clinical trial is delayed, suspended, or terminated, our ability to obtain regulatory approval for that product candidate will be delayed, and the commercial prospects, if any, for the product candidate may suffer. In addition, many of these factors may ultimately lead to the denial of regulatory approval of a product candidate.

***If our competitors develop treatments for any of our product candidates' target indications and those competitor products are approved more quickly, marketed more successfully or demonstrated to be more effective, the commercial opportunity for our product candidates will be reduced or eliminated.***

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. Any of these developments may render one or more of our product candidates obsolete or noncompetitive.

Competitors may seek to develop alternative formulations that do not directly infringe on our in-licensed patent rights. The commercial opportunity for one or more of our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing capabilities.

As a result of these factors, our competitors may obtain regulatory approval for their products more rapidly than we are able to, or may obtain patent protection or other intellectual property or exclusivity rights that limit our ability to develop or commercialize one or more of our product candidates. Our competitors may also develop drugs that are more effective, safe, useful and/or less costly than ours and may be more successful than us in manufacturing and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We will also face competition from these third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in-licensing new product candidates.

***Negative public opinion and increased regulatory scrutiny of the therapies that underpin many of our product candidates may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.***

If any of the technologies underpinning our product candidates, including gene therapy, is claimed to be unsafe, such product candidate may not gain the acceptance of the public or the medical community. The success of our gene therapy platforms in particular depends upon physicians who specialize in treating the diseases targeted by our product candidates prescribing treatments involving our product candidates in lieu of, or in addition to, treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity, could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that do obtain approval and/or a decrease in demand for any such product candidates. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products.

***The making, use, sale, importation, exportation and distribution of controlled substances are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.***

Controlled substances are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the Federal Controlled Substances Act of 1970 (“CSA”) and regulations of the DEA. IV tramadol, under development by our partner company Avenue, will be subject to these regulations.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse and no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Various states also independently regulate controlled substances. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our products classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates and the ability to produce and distribute our products in the volume needed to both meet commercial demand and build inventory to mitigate possible supply disruptions.

Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline.

***The FDA limits regulatory approval for our product candidates to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.***

Any regulatory approval is limited to the indications for use and related treatment of those specific diseases set forth in the approval for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may prescribe drugs for uses that are not described in the product's label or that differ from those tested in clinical studies and approved by the regulatory authorities ("off label uses"), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Such off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the practice of medicine or behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies regarding the promotion of off-label use.

If our promotional activities fail to comply with these regulations or guidelines, we may be subject to compliance or enforcement actions, including Warning Letters or Untitled Letters, by, these authorities. In addition, our failure to follow FDA laws, regulations and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, request a recall, institute fines, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

***If the FDA does not conclude that a product candidate satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidate under Section 505(b)(2) are not as we expect, the approval pathway for the product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization in a timely manner, or at all.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Risks Pertaining to the Need for and Impact of Existing and Additional Financing Activities

***We have historically financed a significant portion of our growth and operations in part through the assumption of debt. Should an event of default occur under any applicable loan documents, our business would be materially adversely affected. Further, our current credit arrangement with Oaktree restricts our and certain of our subsidiaries' and partner companies' abilities to take certain actions.***

At September 30, 2024, the total amount of debt outstanding, net of the debt discount, was $52.5 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest, and/or take possession of any pledged collateral. If an event of default occurs, we may be unable to cure it within the applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment and we may be unable to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, current or future debt obligations may limit our ability to finance future operations, satisfy capital needs, or to engage in, expand or pursue our business activities. Such restrictions may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

On August 27, 2020, we entered into a $60 million senior secured credit agreement (the "Prior Oaktree Agreement" and the debt thereunder, the "Oaktree Note") with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). On July 25, 2024, we, as borrower, entered into a $50.0 million senior secured credit agreement (the "New Oaktree Agreement") with Oaktree. We borrowed $35.0 million under the Agreement on the date of the agreement and are eligible to draw up to an additional $15.0 million with the lenders' consent. The New Oaktree Agreement replaces the Prior Oaktree Agreement. The New Oaktree Agreement contains customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. In addition, the New Oaktree Agreement contains certain financial covenants, including, (i) a requirement that we maintain a minimum liquidity of $7.0 million, which may be reduced or increased as described in the New Oaktree Agreement, and (ii) that product net sales of Journey meet a consolidated minimum net sales amount of $50.0 million on a trailing 12-month basis, tested quarterly, which may be reduced or increased as described in the New Oaktree Agreement (the "Minimum Net Sales Test"), subject to certain exclusions. Failure by the Company to comply with the financial covenants will result in an event of default, subject to certain cure rights with respect to the Minimum Net Sales Test. The breach of any other such provisions (even, potentially, in an immaterial manner) could result in an event of default under the New Oaktree Agreement, the announcement and impact of which could have a negative impact on the trading prices of our securities. The restrictions imposed by such provisions may also inhibit our and certain of our subsidiaries and partner companies' ability to enter into certain transactions or arrangements that management otherwise believes would be in our or such partner companies' best interests, such as dispositions that would result in cash inflows to Fortress and/or our subsidiaries and partner companies, or acquisitions or financings that would promote future growth.

***We have a history of operating losses that is expected to continue, and we are unable to predict the extent of future losses, whether we will be able to sustain current revenues or whether we will ever achieve or sustain profitability.***

We continue to generate operating losses in all periods including losses from operations of approximately $86.5 million and $122.7 million for the nine months ended September 30, 2024 and 2023, respectively and $142.3 million and $203.6 million for the years ended December 31, 2023 and 2022, respectively. At September 30, 2024, we had an accumulated deficit of approximately $734.1 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future, and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and finance investments in certain of our existing and new subsidiaries in accordance with our growth strategy. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity.

Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- one or more of our development-stage product candidates is approved for commercial sale and we decide to commercialize such product(s) ourselves, due to the need to establish the necessary commercial infrastructure to launch and commercialize this product without substantial delays, including hiring sales and marketing personnel and contracting with third parties for manufacturing, testing, warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA or a foreign regulatory authority to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements, depending on the timing of payments we may make or receive under these arrangements;
- there are variations in the level of expenses related to our future development programs;
- we become involved in any product liability or intellectual property infringement lawsuits; and
- there are any regulatory developments affecting our competitors' product candidates.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue from such development-stage products. Our ability to generate revenue from such development-stage products depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire in the future;
- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline. A decline in the value of our company could also cause you to lose all or part of your investment.

***To fund our operations and service our debt securities, which may be deemed to include our Series A Preferred Stock, we will be required to generate a significant amount of cash. Our ability to generate cash depends on a number of factors, some of which are beyond our control, and any failure to meet our debt obligations would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Common Stock and/or Series A Preferred Stock to decline.***

Prevailing economic conditions and financial, business and other factors, many of which are beyond our control, may affect our ability to make payments on our debt. If we do not generate sufficient cash flow to satisfy our debt obligations, we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, reducing or delaying capital investments or seeking to raise additional capital. Alternatively, as we have done in the past, we may also elect to refinance certain of our debt, for example, to extend maturities. Our ability to restructure or refinance our debt will depend on the capital markets and our financial condition at such time. If we are unable to access the capital markets, whether because of the condition of those capital markets or our own financial condition or reputation within such capital markets, we may be unable to refinance our debt. In addition, any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. Our inability to generate sufficient cash flow to satisfy our debt obligations or to refinance our obligations on commercially reasonable terms, or at all, could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline.

Repayment of our indebtedness is dependent in part on the generation of cash flow by Journey and its ability to make such cash available to us, by dividend, debt repayment or otherwise. Journey may not be able to, or may not be permitted to, make distributions to enable us to make payments in respect of our indebtedness. Each of our subsidiaries and partner companies, including Journey, is a distinct legal entity and, under certain circumstances, legal and contractual restrictions may limit our ability to obtain cash from our subsidiaries and partner companies.

Our ability to continue to reduce our indebtedness will depend upon factors including our future operating performance, our ability to access the capital markets to refinance existing debt and prevailing economic conditions and financial, business and other factors, many of which are beyond our control. We can provide no assurance of the amount by which we will reduce our debt, if at all. In addition, servicing our debt will result in a reduction in the amount of our cash flow available for other purposes, including operating costs and capital expenditures that could improve our competitive position and results of operations.

***We may need substantial additional funding and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate one or more of our R&D programs, commercialization efforts or planned acquisitions and potentially change our growth strategy.***

Our R&D programs will require substantial additional capital for research, preclinical testing and clinical trials, establishing pilot scale and commercial scale manufacturing processes and facilities, and establishing and developing quality control, regulatory, marketing, sales, and administrative capabilities to support these programs. We expect to fund our R&D activities from a combination of cash generated from royalties and milestones from our partners in various past, ongoing, and future collaborations, and through additional equity or debt financings from third parties. These financings could depress the trading prices of our Securities. If additional funds are required to support our operations and such funds cannot be obtained on favorable terms, we may not be able to develop products, which will adversely impact our growth strategy.

Our operations have consumed substantial amounts of cash since inception. During the nine months ended September 30, 2024 and 2023, we incurred R&D expenses of approximately $46.9 million and $92.0 million, respectively, and during the years ended December 31, 2023 and 2022, we incurred R&D expenses of approximately $101.7 million and $134.2 million, respectively. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months from the filing of this Quarterly Report on Form 10-Q. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance potential cash needs.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K our public float is less than $75 million, and for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the “baby shelf rules.” SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the registration statement to calculate our public float.

As of the date of the 2023 Form 10-K, our public float was less than $75 million. As a result, for sales following the date of the filing of the 2023 Form 10-K, and until we again have a public float with a value in exceeds of $75 million, if ever, we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statements will also decrease.

Our ability to obtain additional funding when needed, changes to our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our planned R&D activities, expenditures, acquisitions and growth strategy, increased expenses or other events may affect our need for additional capital in the future and require us to seek additional funding sooner or on different terms than anticipated. In addition, if we are unable to raise additional capital when needed, we might have to delay, curtail or eliminate one or more of our R&D programs and commercialization efforts and potentially change our growth strategy, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline. The terms of our existing debt arrangements, including that with Oaktree, have and will continue to inhibit our and our subsidiaries' abilities to raise capital.

***We may be unable to generate returns for our investors if our partner companies and subsidiaries, several of which have limited or no operating history, have no commercialized revenue generating products or, if not yet profitable, cannot obtain additional third-party financing.***

As part of our growth strategy, we have made and will likely continue to make substantial financial and operational commitments in our subsidiaries, which often have limited or no operating history, have no commercialized revenue generating products, and require additional third-party financing to fund product and services development or acquisitions. Our business depends in large part on the ability of one or more of our subsidiaries and/or partner companies to innovate, in-license, develop or acquire successful biopharmaceutical products and/or acquire companies in increasingly competitive and highly regulated markets. If certain of our subsidiaries and/or partner companies do not successfully obtain additional third-party financing to commercialize products or are not acquired in change-of-control transactions that result in cash distributions, as applicable, the value of our businesses and our ownership stakes in our partner companies may be materially adversely affected, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline.

***Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

To the extent that we raise additional capital by issuing Common Stock (or other Securities that are convertible into or exercisable for shares of Common Stock), the share ownership of existing stockholders will be diluted. We have also entered into financing arrangements to raise capital for our subsidiaries under which Common Stock is or may be issuable to investors in lieu of cash, upon certain conditions being met; in the event such issuances take place, they will also be dilutive of the stakes of existing stockholders. Any future debt financings may impose covenants that restrict our operations, including by limiting our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain financial commitments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing or sublicensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

***We have paused dividend payments on our Series A Preferred Stock and may not be able to resume payment of dividends on our Series A Preferred Stock in the future if we have insufficient cash or available "surplus" as defined under Delaware law to make such dividend payments.***

On July 5, 2024, our board of directors paused the payment of dividends on our Series A Preferred Stock until further notice. However, dividends on our Series A Preferred Stock accrue daily, are payable monthly and will continue to accrue from the last date of payment. Our board of directors deemed the foregoing to be in the best interests of the Company and its common stockholders in light of the Company's current and anticipated financial condition and outlook, and after considering its fiduciary duties to the Company's common stockholders and other relevant factors. Our ability to pay cash dividends on our Series A Preferred Stock in the future requires us to have either net profits or positive net assets (total assets less total liabilities) over our capital, and that we have sufficient working capital in order to be able to pay our debts as they become due in the usual course of business. Our ability to pay dividends may also be impaired if any of the risks described in this report were to occur. Also, payment of our dividends depends upon our financial condition and other factors as our board of directors may deem relevant from time to time. We cannot assure you that we will have sufficient cash or "surplus" to resume payment of the cash dividends on the Series A Preferred Stock in a timely manner, or at all.

***We have never paid and currently do not intend to pay cash dividends in the near future, except for the dividend we previously paid on our Series A Preferred Stock. As a result, capital appreciation, if any, will be the sole source of gain for our Common Stockholders.***

We have never paid cash dividends on our Common Stock, or made stock dividends, except for the dividend we previously paid on shares of our Series A Preferred Stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our businesses, and retain our stock positions. In addition, the terms of existing and future debt agreements may preclude us from paying cash or stock dividends. Equally, each of our subsidiaries and partner companies is governed by its own board of directors with individual governance and decision-making regimes and mandates to oversee such entities in accordance with their respective fiduciary duties. As a result, we alone cannot determine the acts that could maximize value to you of such partner companies and subsidiaries in which we maintain ownership positions, such as declaring cash or stock dividends. As a result, capital appreciation, if any, of our Common Stock will be the sole source of gain for holders of our Common Stock for the foreseeable future.

***We have historically relied in part on sales of our common stock and other securities to fund our operations, and our future ability to obtain additional capital through stock sales or other securities offerings may be more costly than in the past, or may not be available to us at all.***

We have historically relied in part on sales of our common stock to fund our operations. For example, we raised an aggregate of approximately $30.2 million in gross proceeds in fiscal years 2022 and 2023 and $6.5 million in gross proceeds in fiscal 2024 to date through the sale of shares of our common stock and other securities in offerings made under a Form S-3 “shelf” registration statement. Using a shelf registration statement to conduct an equity offering to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. We are no longer eligible to file any new shelf registration statements due to non-payment of dividends on our Series A Preferred Stock since July 5, 2024 and, if we do not resume payment of dividends on our Series A Preferred Stock, pay all accumulated dividends and otherwise remain compliant with the other conditions for use of a Form S-3 registration statement by the time we file our next Annual Report on Form 10-K, we will lose the ability to use our currently effective “shelf” registration statement on Form S-3. Accordingly, we may then only be able to conduct additional offerings of our securities under an exemption from registration under the Securities Act or under a Form S-1 registration statement. We would expect either of these alternatives to be a more expensive method of raising additional capital and more dilutive to our stockholders relative to using a shelf registration statement.

Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation

***Future revenue based on sales of our dermatology products, Qbrexza, Accutane, Amzeeq, Zilxi, Targadox, Exelderm and Luxamend, may be lower than expected or lower than in previous periods.***

The vast majority of our operating income for the foreseeable future is expected to come from the sale of our dermatology products through our partner company Journey. Any setback that may occur with respect to such products could significantly impair our financial condition, cash flows and/or operating results and/or reduce the value of our Securities. Setbacks for such products could include, but are not limited to, issues related to: supply chain, shipping; distribution; demand; manufacturing; product safety; product quality; marketing; government regulation, including but not limited to pricing or reimbursement; licensing and approval; intellectual property rights; competition with existing or new products, including third-party generic competition; product acceptance by physicians, other licensed medical professionals, and patients; and higher than expected total rebates, returns or recalls. Also, a significant portion of Journey’s sales derive from products that are without patent protection and/or are or may become subject to third party generic competition; the introduction of new competitor products, or increased market share of existing competitor products, could have a significant adverse effect on our operating income.

***We face challenges as our products face generic competition and/or losses of exclusivity.***

Journey’s products do and may compete with well-established products, both branded and generic, with similar or the same indications. We face increased competition from manufacturers of generic pharmaceutical products, who may submit applications to FDA seeking to market generic versions of our products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents covering certain of our products (if applicable) expire or are successfully challenged through litigation or in USPTO proceedings, if a generic company launches a competing product “at risk,” or when the regulatory or licensed exclusivity for our products (if applicable) expires or is otherwise lost, we may face generic competition as a result.

A significant portion of our sales derive from products that are without patent protection and/or are or may become subject to third-party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income. Three of our marketed products, Qbrexza, Amzeeq, Zilxi, and Emrosi, for which we recently received FDA approval, currently have patent protection. Four of our marketed products, Accutane, Targadox, Luxamend and Exelderm, do not have patent protection or otherwise are not eligible for patent protection.

Accutane currently competes in the Isotretinoin market with five other therapeutically equivalent A/B rated products. Targadox currently competes with one therapeutically equivalent A/B rated generic product. Exelderm may face A/B rated generic competition in the future.

Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version by third-party payors, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Any reduction in sales of our products, or the prices we receive for our products as a result of generic competition could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline.

***Any disruptions to the capabilities, composition, size or existence of Journey's field sales force may have a significant adverse impact on our existing revenue stream. Further, our ability to effectively market and sell any future products that we may develop and for which we receive marketing authorization, will depend on our ability to establish and maintain sales and marketing capabilities or to enter into agreements with third parties to market, distribute and sell any such products.***

Journey's field sales force has been and is expected to continue to be an important contributor to our commercial success. Any disruptions to our relationship with such field sales force or the professional employer organization that employs our field sales force, could materially adversely affect our product sales.

The establishment, development, and/or expansion of a field sales force, either by us or certain of our partners or vendors, or the establishment of a contract field sales force to market any products for which we may have or receive marketing approval is expensive and time-consuming and could delay any such product launch or compromise the successful commercialization of such products. If we are unable to establish and maintain sales and marketing capabilities or any other non-technical capabilities necessary to commercialize any products that may be successfully developed, we will need to contract with third parties to market and sell such products. We may not be able to establish or maintain arrangements with third parties on commercially reasonable terms, or at all.

***If our products are not included in managed care organizations' formularies or coverage by other organizations, our products' utilization and market shares may be negatively impacted, which could have a material adverse effect on our business and financial condition.***

In the United States, continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment of our currently marketed products or those which we may acquire or develop in the future.

Managed care organizations and other third-party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies are based on the prices and therapeutic benefits of available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our products. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, this could have a material adverse effect on our business and financial condition, cash flows and results of operations and could cause the market value of our Securities to decline.

***Reimbursement for our products and product candidates may be limited or unavailable in certain market segments, which could make it difficult for us to sell our products profitably.***

We have obtained approval for some products, and intend to seek approval for other product candidates, to commercialize in both the United States and in countries and territories outside the United States. If we obtain approval in one or more foreign countries, we will be subject to rules and regulations in those countries relating to such products. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates, if approved, will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which pharmaceuticals they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination regarding whether a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- experimental or investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Additionally, while we may seek approval of our product candidates in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

Legislative and regulatory changes to the healthcare systems of the United States and certain foreign countries could impact our ability to sell our products profitably. Several federal agencies including FDA, CMS, DEA and HHS, in addition to state and local governments, regulate drug product development and marketing. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products by revising the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

Since 2003, there have been several other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act" or "ACA," was enacted and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

In the United States there is significant interest in containing healthcare costs and increasing the scrutiny of pharmaceutical pricing practices. Congress has continually explored legislation intended to address the cost of prescription drugs. Notably, the Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

While we cannot predict what additional proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

State legislatures are similarly active in proposing and passing legislation and regulations aimed at controlling pharmaceutical and biological prices and drug cost transparency.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services, including prescription drugs. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and prescription drugs may adversely affect:

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

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidate, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Risks Pertaining to our Business Strategy, Structure and Organization

***We have entered, and will likely in the future enter, into certain collaborations or divestitures which may cause a reduction in our business' size and scope, market share and opportunities in certain markets, or our ability to compete in certain markets and therapeutic categories. We have also entered into several arrangements under which we have agreed to contingent dispositions of subsidiaries, partner companies and/or their assets. The failure to consummate any such transaction may impair the value of such companies and/or assets, and we may not be able to identify or execute alternative arrangements on favorable terms, if at all.***

We have entered into and consummated several partnerships and/or contingent sales of our assets and subsidiaries, including an equity investment and contingent acquisition agreement between Caelum and AstraZeneca (the acquisition component of which has consummated) and a development funding and contingent asset purchase between Cyprium and Sentynl (the acquisition component of which has not yet consummated). Each of these arrangements has been time-consuming and has diverted management's attention. As a result of these consummated/contingent sales, as with other similar transactions that we may complete, we may experience a reduction in the size or scope of our business, our market share in particular markets, our opportunities with respect to certain markets, products or therapeutic categories or our ability to compete in certain markets and therapeutic categories.

In addition, in connection with any transaction involving a (contingent or non-contingent) sale of one of our subsidiaries, partner companies or their assets, we may surrender our ability to realize long-term value from such asset or company, in the form of foregone product sales, royalties, milestone payments, sublicensing revenue or otherwise, in exchange for upfront and/or other payments. In the event, for instance, that a product candidate underpinning any such asset or company is granted FDA approval for commercialization following the execution of documentation governing the sale by us of such asset or company, the transferee of such asset or company may realize tremendous value from commercializing such product, which we would have realized for ourselves had we not executed such sale transaction and been able to achieve applicable approvals independently.

Should we seek to enter into collaborations or divestitures with respect to other assets or companies, we may be unable to consummate such arrangements on satisfactory or commercially reasonable terms within our anticipated timelines. In addition, our ability to identify, enter into and/or consummate collaborations and/or divestitures may be limited by competition we face from other companies in pursuing similar transactions in the biotechnology and pharmaceutical industries.

Any collaboration or divestiture we pursue, whether we are able to complete it or not, may be complex, time consuming and expensive, may divert from management's attention, may have a negative impact on our customer relationships, cause us to incur costs associated with maintaining the business of the targeted collaboration or divestiture during the transaction process and also to incur costs of closing and disposing the affected business or transferring the operations of the business to other facilities. In addition, if such transactions are not completed for any reason, the market price of our Common Stock may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of us generally and a decline in the market price of our Securities.

***We act, and are likely to continue acting, as guarantor and/or indemnitor of the obligations, actions or inactions of certain of our subsidiaries and partner companies. We have also entered into, and may again enter into, certain arrangements with our subsidiaries, partner companies and/or third parties pursuant to which a substantial number of shares of our capital stock may be issued. Depending on the terms of such arrangements, we may be contractually obligated to pay substantial amounts to third parties, or issue a substantially dilutive number of shares of our capital stock, based on the actions or inactions of our subsidiaries and/or partner companies, regulatory agencies or other third parties.***

We act, and are likely to continue acting, as indemnitor of potential losses or liabilities that may be experienced by one or more of our subsidiaries, partner companies and/or their partners or investors. If we become obligated to pay all or a portion of such indemnification amounts, our business and the market value of our Common Stock, Preferred Stock and/or debt securities may be materially adversely affected.

Additionally, we have agreed in the past, and may agree in the future, to act as guarantor in connection with equity or debt raises by our partner companies, pursuant to which we may become obligated either to pay what could be a significant amount of cash or issue what could be a significant number of shares of Common Stock or Preferred Stock if certain events occur or do not occur, which could lead to a depletion of resources or dilution to our Common Stock, or both.

***Our future growth depends in part on our ability to identify and acquire or in-license products and product candidates, and if we are unable to do so, or to integrate acquired products into our operations, we may have limited growth opportunities.***

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including, but not necessarily limited to:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger biopharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors may have access to greater financial resources than us and/or may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

***Certain of our officers and directors serve in similar roles at our partner companies, subsidiaries, related parties and/or other entities with which we transact business or in which we hold significant minority ownership positions, which could result in conflicts of interests relating to ongoing and future relationships and transactions with these parties.***

We share directors and/or officers with certain of our subsidiaries, partner companies, related parties and other entities with which we transact business or in which we hold significant minority ownership positions, and such arrangements could create conflicts of interest in the future, including with respect to the allocation of corporate opportunities. While we believe that we have put in place policies and procedures to identify and mitigate such conflicts, and that any existing agreements that may give rise to such conflicts and any such policies or procedures were negotiated at arm's length in conformity with fiduciary duties, such conflicts of interest, or the appearance of conflict of interest, may nonetheless arise. The existence and consequences of such potential or perceived conflicts could expose us to lost profits, claims by our investors and creditors, and harm to our financial condition, cash flows and/or results of operations.

***Certain of our executives, directors and principal stockholders, whose interests may be adverse to those of our other stockholders, can control our direction and policies.***

Certain of our executive officers, directors and stockholders own nearly or more than 10% of our outstanding Common Stock and, together with their affiliates and related persons, beneficially own a significant percentage of our capital stock. If these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our

assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our Common Stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

***If we acquire, enter into joint ventures with or obtain a controlling interest in, companies in the future, our financial condition, operating results and the value of our Securities may be adversely affected, thereby diluting stockholder value, disrupting our business and/or diminishing the value of our holdings in our partner companies.***

As part of our growth strategy, we might acquire, enter into joint ventures with, or obtain significant ownership stakes in other companies. Acquisitions of, joint ventures with and investments in other companies involve numerous risks, including, but not necessarily limited to:

- risk of entering new markets in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition or investment timely and at a price or on terms and conditions favorable to us;
- the impact of regulatory reviews on a proposed acquisition or investment;
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisitions or investment;
- with respect to an acquisition, difficulties in integrating operations, technologies, services and personnel; and
- potential inability to maintain relationships with customers of the companies we may acquire or invest in.

If we fail to properly evaluate potential acquisitions, joint ventures or other transaction opportunities, we might not achieve the anticipated benefits of any such transaction, we might incur higher costs than anticipated, and management resources and attention might be diverted from other necessary or valuable activities.

***Our results of operations could be adversely affected by economic and political conditions and the effects of these conditions on our business activities.***

Any terrorist attack, other act of violence or war, including military conflicts, could result in increased volatility in, or damage to, the worldwide financial markets and economy. This includes Russia's February 2022 invasion of Ukraine, the conflict between Israel and the Hamas and Hezbollah extremist groups, recent attacks by armed groups on cargo ships in the Red Sea, and tensions across the Taiwan Strait. For instance, the United States or other countries may impose sanctions that restrict doing business in the effected countries and increased military conflict may affect third-party vendors and cause delays.

This risk may be magnified in the case of the conflict between Russia and Ukraine. Russia's invasion and the ensuing response by Ukraine may disrupt our partner companies' ability to conduct clinical trials in Russia, Ukraine, Belarus, and Georgia, and potentially other neighboring countries. Although the impact of Russia's military action is highly unpredictable, certain clinical trial sites may be affected, including those of our partner company Checkpoint in Russia, Ukraine, Belarus, and Georgia. Those clinical trial sites may suspend or terminate trials, and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in clinical trials. For instance, Checkpoint had to terminate their Phase 3 NSCLC trial in the first quarter of 2023 as a result of such conflicts. Alternative sites to fully and timely compensate for clinical trial activities in these areas may not be available, and we may need to find other countries to conduct these clinical trials. Clinical trial interruptions may delay our plans for clinical development and approvals for our product candidates, which could increase costs and jeopardize our ability to commence product sales and generate revenues.

Risks Pertaining to Reliance on Third Parties

***We rely predominantly on third parties to manufacture the majority of our preclinical and clinical pharmaceutical supplies, and we expect to continue to rely heavily on such third parties and other contractors to produce commercial supplies of our product candidates and products, if approved. Further, we rely solely on third parties to manufacture Journey's commercialized products. Such dependence on third-party suppliers could adversely impact our businesses.***

We depend heavily on third party manufacturers for product supply. If our contract manufacturers cannot successfully manufacture material that conforms to applicable specifications and FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for those products. Our third-party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA and comparable agencies and authorities in other jurisdictions to confirm such compliance. In the event that the FDA or such other authorities determine that our third-party suppliers have not complied with cGMPs or comparable regulations, the relevant clinical trials could be terminated or subjected to clinical hold until such time as we are able to obtain appropriate replacement material and/or applicable compliance, and commercial product could be unfit for sale, or if distributed, could be recalled from the market. Any delay, interruption or other issues that arise in the manufacture, testing, packaging, labeling, storage, or distribution of our products as a result of a failure of the facilities or operations of our third-party suppliers to comply with regulatory requirements, pass any regulatory agency inspection or otherwise perform under our agreements with them could significantly impair our ability to develop and commercialize our products and product candidates. In addition, several of our currently commercialized products, sold through our partner company Journey, are produced by a single manufacturer, and, although we closely monitor inventory prophylactically, disruptions to such supply arrangements could adversely affect our ability to meet product demand and therefore diminish revenues. Finally, in light of partner company Mustang's recent reduction in force in April 2024, we may increase our reliance at Mustang on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of one or more product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms, and even if we are able to establish such agreements with third-party manufacturers, reliance entails additional risks.

We also rely on third-party manufacturers to purchase from third-party suppliers the raw materials and equipment necessary to produce product candidates for anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture those products. We do not have direct control over the process or timing of the acquisition of these raw materials by our third-party manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials since such agreements are entered into by our third-party manufacturers and their qualified suppliers. Any significant delay in the supply of raw material components related to an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval.

We do not expect to have the resources or capacity to engage in our own commercial manufacturing of our product candidates, if they received marketing approval, and would likely continue to be heavily dependent upon third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials, as well as our planned dependence on third party manufacturers for any products that may be approved, may adversely affect our ability to develop and commercialize products in a timely or cost-effective manner, or at all. In addition to the manufacturing and supply functions they provide, third-party manufacturers also play a key role in our efforts to obtain marketing approval for our product candidates, by interacting with, providing important information to, and hosting inspections by, applicable regulatory authorities. If a given contract development and manufacturing organization upon whom we rely in such a capacity is unwilling or unable to perform these activities on our behalf, the successful development and/or approval of the applicable product candidate could be delayed significantly.

In addition, because of the sometimes-limited number of third parties who specialize in the development, manufacture and/or supply of our clinical and preclinical materials, we are often compelled to accept contractual terms that we deem less than desirable, including without limitation as pertains representations and warranties, supply disruptions/failures, covenants and liability/indemnification. Especially as pertains liability and indemnification provisions, because of the frequent disparities in negotiating leverage, we are often compelled to agree to low caps on counterparty liability and/or indemnification language that could result in outsized liability to us in situations where we have zero or relatively little culpability.

***We rely heavily on third parties for the development and manufacturing of products and product candidates.***

To date, we have engaged primarily in intellectual property acquisitions, and evaluative and R&D activities and have not generated any revenues from product sales (except through Journey). We have incurred significant net losses since our inception. As of
September 30, 2024, we had an accumulated deficit of approximately $734.1 million, and as of December 31, 2023, we had an accumulated deficit of approximately $694.9 million. We may need to rely on third parties for activities critical to the product candidate development process, including but not necessarily limited to:

- identifying and evaluating product candidates;
- negotiating, drafting and entering into licensing and other arrangements with product development partners; and
- continuing to undertake pre-clinical development and designing and executing clinical trials.

We have also not demonstrated the ability to perform the functions necessary for the successful commercialization of any of our development-stage product candidates, should any of them be approved for marketing. If we were to have any such product candidates approved, the successful commercialization of such products would be dependent on us performing or contracting with third parties for performance, of a variety of critical functions, including, but not necessarily limited to:

- advising and participating in regulatory approval processes;
- formulating and manufacturing products for clinical development programs and commercial sale; and
- conducting sales and marketing activities.

Our operations have been limited to acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of, product candidates, both at the Fortress level and via our subsidiaries and partner companies. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to develop and commercialize potential product candidates, as well as for you to assess the advisability of investing in our securities.

***We rely on third parties to conduct clinical trials. If these third parties do not meet agreed-upon deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful, and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.***

We rely on third-party contract research organizations and site management organizations to conduct most of our preclinical studies and all of our clinical trials for our product candidates. We expect to continue to rely on third parties, such as contract research organizations, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. These CROs, investigators, and other third parties will and do play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators or other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines or fails to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of the clinical trial sites terminates for any reason, we may lose follow-up information on patients enrolled in our ongoing clinical trials unless the care of those patients is transferred to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisers or consultants to us from time to time and receive cash and/or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site, or the FDA's willingness to accept such data, may be jeopardized.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities or potential liability. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with GLPs as appropriate. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may refuse to accept such data, or require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP in strict conformity to cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

We also are required to register certain ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If any of our relationships with these third-party contract research organizations or site management organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

***We rely on clinical and pre-clinical data and results obtained from and by third parties that could ultimately prove to be inaccurate or unreliable.***

As part of our strategy to mitigate development risk, we generally intend on developing product candidates with previously-validated mechanisms of action and seek to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical and pre-clinical data and other results produced or obtained by third parties, which may ultimately prove to be inaccurate or unreliable. If the third-party data and results we rely upon prove to be inaccurate, unreliable, not acceptable by regulatory authorities or not applicable to our product candidates or acquired products, we could make inaccurate assumptions and conclusions about our current or future product candidates and our research and development efforts could be compromised.

***Collaborative relationships with third parties could cause us to expend significant resources and/or incur substantial business risk with no assurance of financial return.***

We anticipate substantial reliance on strategic collaborations for marketing and commercializing our existing product candidates and we may rely even more on strategic collaborations for R&D of other product candidates. We may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited.

If we enter into R&D collaborations during the early phases of drug development, success will, in part, depend on the performance of research collaborators. We may not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our R&D programs. If any research collaborator fails to commit sufficient resources, the preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaboration proposals based upon their assessment of our financial, regulatory or intellectual property positions. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues that might follow are likely to be lower than if we directly marketed and sold products.

Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on, and such collaborations could be more attractive than the one with us for any future product candidate.

Management of our relationships with collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and R&D programs with the respective marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

***The contractual provisions we may be forced to agree upon in services, manufacturing, supply and other agreements may be inordinately one-sided, vis-à-vis current or historical standard market terms (especially as pertains contractual liability and indemnification paradigms), and as a result we may be subject to liabilities that are not attributable to our own actions or the actions of our personnel.***

There is a finite number of service providers who can perform the services or produce the materials or product candidates that we need, and we therefore often have a limited number of options in choosing such service providers. The standard market terms in many of the agreements into which we customarily enter with such service providers are subject to evolution over time, often-times in favor of our counterparties. Also, some such agreements are "adhesion contracts" under which our contractual counterparties refuse to entertain any modifications to their template documentation. One area where service providers often have and exert leverage over us is the negotiation of liability language – specifically in broadly scoped indemnification by us of service providers and/or the application of liability damages "caps" to certain of such service providers' indemnification obligations. In any circumstance where we've been compelled to agree to such language, it is conceivable that we will be liable to third parties for liabilities in excess of such caps that are attributable to the actions, forbearances and/or culpability of such service providers and their indemnitees (and not to those of us and our personnel).

Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

***If we are unable to obtain and maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.***

Our success depends, in large part, on our ability to obtain patent protection for our product candidates and their formulations and uses. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in obtaining patents or what the scope of an issued patent may ultimately be. These risks and uncertainties include, but are not necessarily limited to, the following:

- patent applications may not result in any patents being issued, or the scope of issued patents may not extend to competitive product candidates and their formulations and uses developed or produced by others;
- our competitors, many of which have substantially greater resources than we or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that may limit or interfere with our abilities to make, use, and sell potential product candidates, file new patent applications, or may affect any pending patent applications that we may have;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

In addition, patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the PTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent positions. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technologies or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Third parties are often responsible for maintaining patent protection for our product candidates, at our and their expense. If that party fails to appropriately prosecute and maintain patent protection for a product candidate, our abilities to develop and commercialize products may be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Such a failure to properly protect intellectual property rights relating to any of our product candidates could have a material adverse effect on our financial condition and results of operations.

In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents.

We and our licensors also rely on trade secrets and proprietary know-how to protect product candidates. Although we have taken steps to protect our and their trade secrets and unpatented know-how, including entering into confidentiality and non-use agreements with third parties, and proprietary information and invention assignment agreements with employees, consultants and advisers, third parties may still come upon this same or similar information independently. Despite these efforts, any of these parties may also breach the agreements and may unintentionally or willfully disclose our or our licensors' proprietary information, including our trade secrets, and we may not be able to identify such breaches or obtain adequate remedies. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our or our licensors' trade secrets were to be lawfully obtained or independently developed by a competitor, we and our licensors would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our or our licensors' trade secrets were to be disclosed to or independently developed by a competitor, our competitive positions would be harmed.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the US. The patent situation outside the US is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the US, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than US law does. We might also become involved in derivation proceedings in the event that a third party misappropriates one or more of our inventions and files their own patent application directed to such one or more inventions. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention (or that a third party derived an invention from us) would be unsuccessful, resulting in a material adverse effect on our US patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the US and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the US have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection.

Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the US. Accordingly, we cannot predict the breadth of claims that may be allowed and remain enforceable in our patents or in those licensed from a third party.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include changes to transition from a “first-to-invent” system to a “first inventor-to-file” system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a less burdensome, quicker and less expensive process for challenging issued patents. The PTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

We also may rely on the regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is generally 12 years from the date of marketing approval (depending on the nature of the specific product), there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect our business.

***If we or our licensors are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our success also depends on our ability, and the abilities of any of our respective current or future collaborators, to develop, manufacture, market and sell product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our or our licensors' intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we or our licensors are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or such licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we and our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a US patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the PTO to determine priority of invention in the US. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to, among other things:

- obtain additional licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign products or processes to avoid infringement, which may demand substantial funds, time and resources and which may result in inferior or less desirable processes and/or products;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross-licenses to our product candidates; and/or
- defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of financial and management resources.

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

Competitors may infringe our or our licensors' patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging invalidity of our or our licensors' patents or that we infringe their patents; or provoke those parties to petition the PTO to institute *inter partes* review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensor's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could likewise put pending patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

***We in-license from third parties a majority of the intellectual property needed to develop and commercialize products and product candidates. As such, any dispute with the licensors or non-performance of such license agreements may adversely affect our ability to develop and commercialize the applicable product candidates.***

The patents, patent applications and other intellectual property rights underpinning the vast majority of our existing product candidates were in-licensed from third parties. Under the terms of such license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach. The licenses require us to make annual, milestone or other payments prior to commercialization of any product, and our ability to make these payments depends on the ability to generate cash in the future. These license agreements also generally require the use of diligent and reasonable efforts to develop and commercialize product candidates.

If there is any conflict, dispute, disagreement or issue of non-performance between us or one of our partners, on the one hand, and the respective licensing partner, on the other hand, regarding the rights or obligations under the license agreements, including any conflict, dispute or disagreement arising from a failure to satisfy payment obligations under such agreements, the ability to develop and commercialize the affected product candidate may be adversely affected.

The types of disputes that may arise between us and the third parties from whom we license intellectual property include, but are not necessarily limited to:

- the scope of rights granted under such license agreements and other interpretation-related issues;
- the extent to which our technologies and processes infringe on intellectual property of the licensor that is not subject to such license agreements;
- the scope and interpretation of the representations and warranties made to us by our licensors, including those pertaining to the licensors' right title and interest in the licensed technology and the licensors' right to grant the licenses contemplated by such agreements;
- the sublicensing of patent and other rights under our license agreements and/or collaborative development relationships, and the rights and obligations associated with such sublicensing, including whether or not a given transaction constitutes a sublicense under such license agreement;
- the diligence and development obligations under license agreements (which may include specific diligence milestones) and what activities or achievements satisfy those diligence obligations;
- whether or not the milestones associated with certain milestone payment obligations have been achieved or satisfied;
- the applicability or scope of indemnification claims or obligations under such license agreements;
- the permissibility and advisability of, and strategy regarding, the pursuit of potential third-party infringers of the intellectual property that is the subject of such license agreements;
- the calculation of royalty, milestone, sublicense revenue and other payment obligations under such license agreements;
- the extent to which rights, if any, are retained by licensors under such license agreements;
- whether or not a material breach has occurred under such license agreements and the extent to which such breach, if deemed to have occurred, is or can be cured within applicable cure periods, if any;
- disputes regarding patent filing and prosecution decisions, as well as payment obligations regarding past and ongoing patent expenses;
- intellectual property rights resulting from the joint creation or use of intellectual property (including improvements made to licensed intellectual property) by our and our partners' licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of such third-party licensing partners. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreements, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Risks Pertaining to the Commercialization of Product Candidates

***If any of our product candidates are successfully developed and receive regulatory approval but do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates, if approved, generate from sales will be limited.***

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates, if approved, by third-party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such products as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of such products over alternative treatments;
- the safety of such products in a broader patient group (i.e., based on actual use);
- the availability, cost and benefits of treatment, in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- changes in regulatory requirements by government authorities for such products;
- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions;
- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and in turn we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

***Even if approved, any product candidates that we may develop and market may be later withdrawn from the market or subject to promotional limitations.***

We may not be able to obtain the desired labeling claims or scheduling classifications necessary or desirable for the promotion of our marketed products (or our product candidates if approved). We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval while our products are on the market, the FDA or a comparable regulatory authority in another jurisdiction may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to complete. In addition, if manufacturing problems occur, regulatory approval may be impacted or withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of such products if approved.

***We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization, if approved.***

The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product candidate or product we develop, license, or acquire allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate or product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop, license or acquire;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the ability to commercialize our product candidate or future product candidates.

We will obtain limited product liability insurance coverage for all of our upcoming clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Additionally, we have entered into various agreements under which we indemnify third parties for certain claims relating to product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

***Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with products, when and if any of them are approved.***

Any product for which we obtain marketing approval, along with the authorized manufacturing facilities, processes and equipment, post-approval clinical data, labeling, advertising and promotional activities for such product, will remain subject to ongoing regulatory requirements governing drug or biological products, as well as review by the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping, and requirements regarding company presentations and interactions with healthcare professionals. Even if we obtain regulatory approval for a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed or subject to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We also may be subject to state laws and registration requirements covering the distribution of drug products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on product manufacturing, distribution or use;
- restrictions on the labeling or marketing of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters, untitled letters, or Form 483s;
- recalls or other withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- fines;
- suspension or withdrawal of marketing or regulatory approvals;
- refusal to permit the import or export of products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we or our suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaborators may be subject to the actions listed above, including losing marketing approval for product candidates when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline.

***We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.***

A pharmaceutical product cannot be marketed in the U.S. or other countries until the relevant governmental authority has completed a rigorous and extensive regulatory review process, including approval of a brand name. Any brand names we intend to use for our product candidates in the U.S. will require approval from the FDA regardless of whether we have secured a formal trademark registration from the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we could lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

***Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of our product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to "covered recipients," which include physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives and teaching hospitals) and applicable manufacturers. Applicable group purchasing organizations also are required to report annually to CMS the ownership and investment interests held by the physicians and their immediate family members. The SUPPORT for Patients and Communities Act added to the definition of covered recipient practitioners including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives effective in 2022; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our businesses. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our businesses.

***As we continue to execute our growth strategy, we may be subject to further government regulation which could adversely affect our financial results, including without limitation the Investment Company Act of 1940.***

If we engage in business combinations and other transactions that result in holding minority or non-control investment interests in a number of entities, we may become subject to regulation under the Investment Company Act of 1940, as amended (the "Investment Company Act"). If we do become subject to the Investment Company Act, we would be required to register as an investment company and could be expected to incur significant registration and compliance costs in the future.

***Recent U.S. Supreme Court decisions could create uncertainty in the life sciences space that could negatively impact our business.***

Three decisions from the U.S. Supreme Court in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes.

General and Other Risks

***Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties' cybersecurity.***

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality, availability and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk.

We are in the process of implementing our internal security and business continuity measures and developing our information technology infrastructure. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, third-party software, data center facilities, lab equipment, and connection to the internet, face the risk of breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware and other malicious code, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, and could result in financial, legal, business, and reputational harm to us. For example, in 2021, our partner company Journey was the victim of a cybersecurity incident that affected its accounts payable function and led to approximately $9.5 million in wire transfers being misdirected to fraudulent accounts. The details of the incident and its origin were investigated with the assistance of third-party cybersecurity experts working at the direction of legal counsel. The matter was reported to the Federal Bureau of Investigation and does not appear to have compromised any personally identifiable information or protected health information. The federal government has been able to seize a significant amount of cryptocurrency assets associated with the breach. Once the cryptocurrency has been converted back into U.S. dollars, Journey expects to receive a notification letter to initiate the return of the cash. This process could take as long as six months or more to complete. Fortress and Journey may incur additional expenses and losses as a result of this cybersecurity incident, including those related to investigation fees and remediation costs.

In addition, the loss or corruption of, or other damage to, clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates or any future drug candidates and to conduct clinical trials, and similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Sophisticated cyber attackers (including foreign adversaries engaged in industrial espionage) are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary information, including trade secrets. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

Any security breach or other event leading to the loss or damage to, or unauthorized access, use, alteration, disclosure, or dissemination of, personal information, including personal information regarding clinical trial subjects, contractors, directors, or employees, our intellectual property, proprietary business information, or other confidential or proprietary information, could directly harm our reputation, enable competitors to compete with us more effectively, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Each of the foregoing could result in significant legal and financial exposure and reputational damage that could adversely affect our business. Notifications and follow-up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. We expect to incur significant costs in an effort to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, and actual, potential, or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants. We may face increased costs and find it necessary or appropriate to expend substantial resources in the event of an actual or perceived security breach.

The costs related to significant security breaches or disruptions could be material, and our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

***We may not be able to hire or retain key officers or employees needed to implement our business strategy and develop products and businesses.***

Our success depends on the continued contributions of our executive officers, financial, scientific, and technical personnel and consultants, and on our ability to attract additional personnel as we continue to implement growth strategies and acquire and invest in companies with varied businesses. During our operating history, many essential responsibilities have been assigned to a relatively small number of individuals. However, as we continue to implement our growth strategy, the demands on our key employees will expand, and we will need to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel, or our inability to attract additional personnel to fill critical positions, could adversely affect our business.

We currently depend heavily upon the efforts and abilities of our management team and the management teams of our partners. The loss or unavailability of the services of any of these individuals could have a material adverse effect on our business, prospects, financial condition and results. In addition, we have not obtained, do not own, and are not the beneficiary of key-person life insurance for any of our key personnel. We only maintain a limited amount of directors' and officers' liability insurance coverage. There can be no assurance that this coverage will be sufficient to cover the costs of the events that may occur, in which case, there could be a substantial impact on our ability to continue operations.

***Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third-party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with cGMPs, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee, consultant, or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other civil and/or criminal sanctions.

We receive a large amount of proprietary information from potential or existing licensors of intellectual property and potential acquisition target companies, all pursuant to confidentiality agreements. The confidentiality and proprietary invention assignment agreements that we have in place with each of our employees and consultants prohibit the unauthorized disclosure of such information, but such employees or consultants may nonetheless disclose such information through negligence or willful misconduct. Any such unauthorized disclosures could subject us to monetary damages and/or injunctive or equitable relief. The notes, analyses and memoranda that we have generated based on such information are also valuable to our businesses, and the unauthorized disclosure or misappropriation of such materials by our employees and consultants could significantly harm our strategic initiatives – especially if such disclosures are made to our competitor companies.

***We may be subject to claims that our employees and/or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.***

As is common in the biopharmaceutical industry, we rely on employees and consultants to assist in the development of product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biopharmaceutical companies, including our competitors or potential competitors. We may become subject to claims related to whether these individuals have inadvertently or otherwise used, disclosed or misappropriated trade secrets or other proprietary information of their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending these claims, litigation could result in substantial costs and be a distraction to management and/or the employees or consultants that are implicated.

***The market price of our securities may be volatile and may fluctuate in a way that is disproportionate to our operating performance.***

The stock prices of our securities may experience substantial volatility as a result of a number of factors, including, but not necessarily limited to:

- announcements we make regarding our current product candidates, acquisition of potential new product candidates and companies and/or in-licensing through multiple partners/affiliates;
- sales or potential sales of substantial amounts of our Common Stock;
- issuance of debt or other securities;
- our delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of any of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;

- developments concerning our licensors and/or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- unstable regional political and economic conditions;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market prices of our securities, regardless of our actual operating performance.

***Sales or other issuances of a substantial number of shares of our Common Stock, or the perception that such sales or issuances may occur, may adversely impact the price of our Common Stock.***

Almost all of our outstanding shares of our Common Stock, inclusive of outstanding equity awards, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), or an effective registration statement. In addition, pursuant to our current shelf registration statements on Form S-3, from time to time we may issue and sell shares of our Common Stock or Series A Preferred Stock having an aggregate offering price of up to $50 million. Any sale of a substantial number of shares of our Common Stock or our Series A Preferred Stock could cause a drop in the trading price of our Common Stock or Series A Preferred Stock on the Nasdaq Stock Market.

***We may not be able to manage our anticipated growth, which may in turn adversely impact our business.***

We will need to continue to expend capital on improving our infrastructure to address our anticipated growth. Acquisitions of companies or products could place a strain on our management, and administrative, operational and financial systems. In addition, we may need to hire, train, and manage more employees, focusing on their integration with us and corporate culture. Integration and management issues associated with increased acquisitions may require a disproportionate amount of our management's time and attention and distract our management from other activities related to running our business.

***A catastrophic disaster could damage our facilities beyond insurance limits or cause us to lose key data, which could cause us to curtail or cease operations.***

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. We have property, liability and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects.

Any of the aforementioned circumstances, may also impede our employees' and consultants' abilities to provide services in-person and/or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of "force majeure" clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such "force majeure" clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time-consuming.

***Our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.***

We may, from time to time, carry net operating loss carryforwards ("NOLs") as deferred tax assets on our balance sheet. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage- point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use all of its pre-change NOLs and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which changes are outside our control. As a result, our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We, and/or third parties on our behalf, may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations may also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our respective resources, and clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted in connection with the storage or disposal of biological or hazardous materials.

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

***Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business or the business of our partners.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, ability to accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business or the business of our partners. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough nonessential FDA employees and stop routine activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If the timing of FDA's review and approval of new products is delayed, the timing of our or our partners' development process may be delayed, which could result in delayed milestone revenues and materially harm our operations or business.

***We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. Also, if we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Securities.***

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act ("SOX"), as well as rules subsequently implemented by the SEC, and the rules of the Nasdaq Stock Exchange. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

SOX requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of SOX. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

***Provisions in our certificate of incorporation, our bylaws and Delaware law might discourage, delay or prevent a change in control of our Company or changes in our management and, therefore, depress the trading price of our Common Stock or other Securities.***

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers and/or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our Common Stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you would receive a premium for your ownership of our Securities through an acquisition.

***If we fail to comply with the continuing listing standards of Nasdaq, our common stock could be delisted from the exchange.***

We have previously failed to satisfy certain continued listing rules of the Nasdaq, including rules requiring that the minimum trading price of our Common Stock not close below $1.00 per share for 30 consecutive business days. If we again are unable to meet the continued listing requirements, our Common Stock and Preferred Stock may be subject to delisting from The Nasdaq Capital Market if we are unable to regain compliance with such rules. The delisting of our Securities from the Nasdaq may decrease the market liquidity and market price of our Common Stock and Preferred Stock.

***Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. For example, the United States recently passed the Inflation Reduction Act, which provides for a minimum tax equal to 15% of the adjusted financial statement income of certain large corporations, as well as a 1% excise tax on certain share buybacks by public corporations that would be imposed on such corporations. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

***Fluctuations in interest rates may negatively impact the rate of return that we realize on the investment securities that we hold.***

We customarily invest a significant portion of our cash in Certificate of Deposit Account Registry Service (“CDARS”) accounts, which bear interest income to us that fluctuates according to adjustments in the target federal funds rate effected by the U.S. Federal Reserve’s Federal Open Market Committee (“FOMC”). The FOMC recently lowered the target federal funds rate and is anticipated by some to effect further decreases over the coming weeks and months, actions which have decreased, and could further decrease, the amount of interest income that we generate on our CDARS and on other short-term cash equivalent investment securities that we may hold.

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

None.

**Item 3. Defaults Upon Senior Securities**

On July 5, 2024, Fortress announced that the Company’s Board of Directors had decided to pause the monthly dividend of $0.1953125 per share of the Company’s Series A Preferred Stock. In accordance with the terms of the Series A Preferred Stock, dividends on the Series A Preferred Stock will continue to accrue and cumulate until such dividends are authorized or declared. The pausing of these dividends will defer approximately $0.7 million in cash dividend payments each month. The Board intends to revisit its decision regarding the monthly dividend regularly and will assess the profitability and cash flow of the Company to determine whether and when the pause should be lifted.

During the three months ended September 30, 2024, no dividends were declared by the Board of Directors. At September 30, 2024, the Company had total undeclared dividends of approximately $2.0 million, which represents the cumulated (but undeclared) dividends due to Series A Preferred shareholders on September 30, 2024.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

**Exhibit Index**

| Exhibit Number | Exhibit Title |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. (formerly Coronado Biosciences, Inc.) dated April 21, 2010 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10 (file No. 000-54463) filed with the SEC on July 15, 2011). |
| 3.2 | First Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated May 20, 2011 (incorporated by reference to Exhibit 3.2 of the Registrant's Form 10 (file No. 000-54463) filed with SEC on July 15, 2011). |
| 3.3 | Second Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated October 1, 2013 (incorporated by reference to Exhibit 3.8 of the Registrant's Annual Report on Form 10-K (file No. 001-35366) filed with SEC on March 14, 2014). |
| 3.4 | Third Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated April 22, 2015 (incorporated by reference to Exhibit 3.9 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on April 27, 2015). |
| 3.5 | Certificate of Designation of Rights and Preferences of the Fortress Biotech, Inc. 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on November 7, 2017). |
| 3.6 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 18, 2020 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on June 19, 2020). |
| 3.7 | Certificate of Amendment to the Certificate of Designations and Rights and Preferences of the Fortress Biotech, Inc. 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock under the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 18, 2020 (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 19, 2020). |
| 3.8 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 23, 2021 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-K (file No. 001-35366) filed with SEC on June 23, 2021). |
| 3.9 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated July 8, 2022 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-35366) filed with SEC on July 11, 2022). |
| 3.10 | Certificate of Amendment of the Amended and Restated Certificate of Incorporation, as Amended, of Fortress Biotech, Inc. dated October 9, 2023 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-35366) filed with SEC on October 10, 2023. |
| 3.11 | Fourth Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on June 25, 2024). |
| 4.1 | Form of Warrant issued to certain affiliates of Oaktree Fund Administration, LLC on July 25, 2024 (incorporated by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form S-1 (Reg. No. 33-282384) filed with the SEC on September 27, 2024). |

| | |
|---|---|
| 4.2 | Form of PIPE Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on September 23, 2024). |
| 10.1 | Form of Securities Purchase Agreement, dated September 19, 2024, by and among the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on September 23, 2024). |
| 10.2 | Placement Agent Agreement entered into by and between the Company and the Placement Agent, dated September 19, 2024 (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on September 23, 2024). |
| 10.3 | Credit Agreement entered into by and among Fortress Biotech, Inc., the lenders from time to time party thereto, and Oaktree Fund Administration, LLC on July 25, 2024 (incorporated by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form S-1 (Reg. No. 33-282384) filed with the SEC on September 27, 2024). |
| 10.4 | Asset Purchase Agreement, dated as of July 15, 2024, between Urica Therapeutics, Inc. and Crystalys Therapeutics, Inc.(*)(***) |
| 10.5 | Royalty Agreement, dated as of July 15, 2024, between Urica Therapeutics, Inc. and Crystalys Therapeutics, Inc.(*)(***) |
| 31.1 | Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.(*) |
| 31.2 | Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.(*) |
| 32.1 | Certification of the Chairman, President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(**) |
| 32.2 | Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(**) |
| 101.INS | Inline XBRL Instance Document.(*) |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document.(*) |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document.(*) |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document.(*) |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document.(*) |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document.(*) |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). |

* Filed herewith.
** Furnished herewith.
*** Certain portions of this exhibit have been omitted pursuant to Item 60(b)(10) of Regulation S-K.

**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.

November 14, 2024

FORTRESS BIOTECH, INC.

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer (Principal Executive Officer)

November 14, 2024

By: /s/ David Jin
David Jin, Chief Financial Officer (Principal Financial Officer)

**Exhibit 10.4**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

# ASSET PURCHASE AGREEMENT

dated as of July 15, 2024

by and among

**CRYSTALYS THERAPEUTICS, INC.**

AND

**URICA THERAPEUTICS, INC.**

**TABLE OF CONTENTS**



**EXHIBITS**

**ASSET PURCHASE AGREEMENT**

This Asset Purchase Agreement (this "**Agreement**") is made and entered into as of July 15, 2024 by and between **CRYSTALYS THERAPEUTICS, INC.**, a Delaware corporation having a place of business at 100 Pine St. Ste #1250, San Francisco, CA 94111 ("**Buyer**"), and **URICA THERAPEUTICS, INC.**, a Delaware corporation having a place of business at 1111 Kane Concourse Suite 301, Bay Harbor Islands, FL 33154 ("**Seller**"). Buyer and Seller are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

**RECITALS**

**WHEREAS**, Seller is in the process of conducting research and development of the development-stage molecule known as dotinurad in an orally available form; and

**WHEREAS**, Seller desires to sell, transfer, convey, assign and deliver to Buyer, and Buyer desires to purchase and acquire from Seller, the Acquired Assets, and Seller desires to assign to Buyer and Buyer desires to assume from Seller the Assumed Liabilities, upon and subject to the conditions hereinafter specified, and in connection therewith, the Buyer and Seller shall enter into the Royalty Agreement (as defined below), the Security Agreement (as defined below), and the Stock Issuance Agreement (as defined below).

**AGREEMENT**

**NOW, THEREFORE**, in consideration of the foregoing premises and the respective representations, warranties, covenants, agreements and conditions contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

## 1. DEFINITIONS

Capitalized terms used in this Agreement (other than the headings of the Sections or Articles) have the following meanings set forth in this Article 1, or, if not listed in this Article 1, the meanings as designated in the text of this Agreement.

1.1 "**Accounting Standards**" means, with respect to a Party, (a) United States Generally Accepted Accounting Principles or (b) to the extent applicable, International Financial Reporting Standards as issued by the International Accounting Standards Board, in each case, consistently applied by such Party.

1.2 "**Affiliate**" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of the definition in this Section 1.2, the word "**control**" (including, with correlative meaning, the terms "**controlled by**" or "**under the common control with**") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of at least 50% of the voting stock of such entity, or by contract or otherwise. The Parties acknowledge that in the case of entities organized under the Laws of certain countries where the maximum percentage ownership permitted by law for a foreign investor is less than 50%, such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding anything to the contrary herein, whether prior to or following the Closing, neither Buyer nor its Affiliates shall be deemed an Affiliate of Seller under this Agreement, and Seller shall not be deemed an Affiliate of Buyer or its Affiliates under this Agreement.

1.3 "**Assignment and Assumption Agreement**" means the Assignment and Assumption Agreement and between Seller and Buyer or one of its Affiliates, substantially in the form attached hereto as Exhibit A.

1.4 "**Assumed Contracts**" means all of the Contracts set forth on Schedule 1.4, including the Seller Intellectual Property Licenses.

1.5 "**Bill of Sale**" means the Bill of Sale and between Seller and Buyer or one of its Affiliates, substantially in the form attached hereto as Exhibit B.

1.6 "**Business Day**" means any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by Law to be closed in California.

1.7 "**Clawback Expiration Date**" means the first Business Day following the date that is 12 months after the Closing Date.

1.8 "**Clawback Shares**" means an aggregate number of shares of Common Stock of Buyer equal to 10% of the Stock Consideration issued to Seller at Closing.

1.9 "**Closing**" means the closing of the purchase and sale of the Acquired Assets and assignment and assumption of the Assumed Liabilities, each as contemplated by this Agreement.

1.10 "**Code**" means the Internal Revenue Code of 1986, as amended.

1.11 "**Common Stock of Buyer**" means the Buyer's common stock, par value $0.00001 per share.

1.12 "**Compound**" means the chemical compound with the IUPAC name (3,5-Dichloro-4-hydroxyphenyl)(1,1-dioxo-1,2-dihydro-3H-1λ6-1,3-benzothiazol-3-yl) methanone (IUPAC), including any salt, hydrate, racemates, isomers, polymorph, metabolites, or prodrugs thereof.

1.13 "**Contract**" means any contract, agreement, indenture, note, bond, loan, license, instrument, lease, commitment, plan or other arrangement.

1.14 "**Convertible Notes**" means, collectively, the Outstanding Notes and the Future Notes.

1.15 "**Data Protection Requirements**" means all of the following to the extent relating to the treatment of data (including any access, collection, use, disclosure, storage or processing thereof) or otherwise relating to privacy, security, or security breach notification requirements and applicable to Acquired Assets, or to any of the IT Systems: (a) Seller's own rules, policies, and procedures; (b) all applicable Laws; and (c) Contracts into which Seller has entered or is otherwise bound.

1.16 "**Disclosure Schedule**" means a schedule executed and delivered by Seller to Buyer as of the date hereof which sets forth exceptions to the representations and warranties made by Seller contained in this Agreement and certain other information called for by this Agreement.

1.17 "**Dollars**" or "**$**" means United States Dollars.

1.18 "**Dotinurad IND**" means IND # 157915.

1.19 "**Excluded Taxes**" means: (i) all Taxes imposed on or with respect to the Acquired Assets or otherwise with respect to the ownership of the Acquired Assets, in each case for Pre-Closing Tax Periods, but excluding any Property Taxes to the extent specifically allocated to Buyer pursuant to Section 6.4(b); (ii) all Taxes of Seller or any of its Affiliates, including under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local or foreign Law), as a transferee or successor, by contract or otherwise for any Tax period, and including any Taxes of Seller or its Affiliates arising out of the sale of the Acquired Assets pursuant to this Agreement; and (iii) any Transfer Taxes required to be borne by Seller pursuant to Section 4.4. For the avoidance of doubt, in no event shall Buyer or any of its subsidiaries be deemed to be an "Affiliate" of Seller for purposes of this definition.

1.20 "**Export Control Laws**" means (a) all applicable trade, export control, import, and antiboycott laws and regulations imposed, administered, or enforced by the U.S. government, including the Arms Export

Control Act (22 U.S.C. §1778), the International Emergency Economic Powers Act (50 U.S.C. §§1701–1706), Section 999 of the Internal Revenue Code, the U.S. customs laws at Title 19 of the U.S. Code, the Export Control Reform Act of 2018 (50 U.S.C. §§4801-4861), the International Traffic in Arms Regulations (22 C.F.R. Parts 120–130), the Export Administration Regulations (15 C.F.R. Parts 730-774), the U.S. customs regulations at 19 C.F.R. Chapter I, and the Foreign Trade Regulations (15 C.F.R. Part 30); and (b) all applicable trade, export control, import, and antiboycott laws and regulations imposed, administered or enforced by any other country, except to the extent inconsistent with U.S. law.

1.21 "**FDA**" means the United States Food and Drug Administration, or any successor thereto.

1.22 "**FDA Meeting**" means an end of phase 2 meeting to be held between Buyer and the FDA to discuss the development of the Compound.

1.23 "**FDCA**" means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the rules and regulations promulgated thereunder.

1.24 "**Fraud**" means a claim for Delaware common law fraud brought in respect of a representation or warranty made in this Agreement. For the avoidance of doubt, "Fraud" does not include any claim for equitable fraud, promissory fraud, unfair dealings fraud, or any torts (including a claim for fraud) based on negligence.

1.25 "**Fuji License Agreement**" means that certain License Agreement, dated as of November 25, 2020, by and between Fuji Yakuhin Co. Ltd. ("**Fuji**") and Seller, as amended by that certain First Amendment to License Agreement, dated as of August 16, 2022, as further amended by that certain Second Amendment to License Agreement, dated as of November 2, 2022, including any subsequent amendments, restatements or modifications thereof and any further agreements entered into by Fuji and Buyer or its Affiliates relating to the Compound and/or any data provided by Fuji used to obtain regulatory approval of dotinurad.

1.26 "**Future Notes"** means those certain convertible promissory notes expected to be issued by Buyer following the Closing in the aggregate principal amount of up to $5,499,994 on the same terms as the Outstanding Notes.

1.27 "**Governmental Authority**" means any multi-national, federal, state, local, municipal, or provincial government; any governmental or quasi-governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal); any tribunal, court of competent jurisdiction, administrative agency or commission or other governmental authority or body exercising or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power of any nature (in each case whether federal, state, local, foreign, international or multinational); any Regulatory Authority; or any arbitrator with authority to bind a party at Law.

1.28 "**Healthcare Laws**" means all healthcare Laws applicable to the ownership, testing, development, sale, marketing, manufacture, packaging, processing, use, distribution, storage, import, export, or disposal of the Compound, including but not limited to, the FDCA, the Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to healthcare fraud and abuse, including but not limited to 18 U.S.C. §§ 286, 287, 1035, 1347, 1349 and the healthcare fraud criminal provisions under HIPAA (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), HIPAA and similar state and foreign data privacy and security laws such as the European Union General Data Protection Regulation, Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), any other healthcare Law governing a government healthcare program, and any and all other comparable state, local, federal or foreign healthcare Laws and the regulations promulgated pursuant to such Laws, each as amended from time to time.

1.29 "**HIPAA**" means the U.S. Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.) as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. § 17921 et seq.), and all regulations promulgated thereunder.

1.30 "**IND**" means an investigational new drug application submitted to the FDA pursuant to 21 C.F.R. Part 312 for allowance to initiate human clinical trials in the United States, including all amendments that may be submitted with respect to the foregoing.

1.31 "**Indebtedness**" means as to any Person at any time: (a) obligations of such Person for borrowed money (including any unpaid principal, premium, accrued and unpaid interest, related expenses, prepayment penalties, commitment and other fees, reimbursements, indemnities and all other amounts payable in connection therewith); (b) obligations of such Person evidenced by bonds, notes, debentures or other similar instruments; (c) all liabilities of such Person in respect of the deferred purchase price of goods, property, plant, equipment, assets or services or any conditional sale or other title retention agreements with respect to acquired property with respect to which a Person is liable, contingently or otherwise as obligor or otherwise (including all obligations under noncompete, consulting or similar arrangements); (d) capitalized lease obligations of such Person; (e) all obligations under any derivative, swap or hedging arrangements; (f) indebtedness or other obligations of others guaranteed by such Person; (g) obligations secured by a Lien existing on any property or asset owned by such Person; (h) reimbursement obligations of such Person relating to letters of credit, bankers' acceptances, surety or other bonds or similar instruments; and (i) Liabilities of such Person relating to any unfunded retirement plan contributions or overfunded retirement plan contributions, and any unsatisfied obligation for "withdrawal liability" to any employee benefit plan.

1.32 "**Independent Accountant**" means an impartial nationally recognized accounting firm of independent certified public accountants mutually agreed by Buyer and Seller, other than Buyer or Seller's respective accountants.

1.33 "**Intellectual Property Rights**" means all intellectual property rights of the following types, whether registered or unregistered, which may exist or be created under the laws of any jurisdiction: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, and moral rights; (b) trademark, trade name, service mark and service name rights and rights in, logos, business names, slogans, hash tags, social media pages, and similar means of identification and similar rights, and the goodwill associated with the foregoing; (c) Know-How and confidential or proprietary information; (d) Patents; (e) rights in databases, information and data (including preclinical data, non-clinical data and clinical data, knowledge databases, customer lists and customer databases); (f) URL and domain name registrations; (g) inventions; and (h) any other proprietary rights to intellectual property now known or hereafter recognized in any jurisdiction worldwide.

1.34 "**IRS**" means the United States Internal Revenue Service.

1.35 "**IT System**" means the communications networks, data centers, software, computer hardware (whether general or special purpose), networks, interfaces, platforms, servers, and computer systems, including any outsourced systems and processes that are owned or used by Seller in the operation of its business.

1.36 "**Know-How**" means know-how, Trade Secrets, chemical and biological materials, formulations, information, documents, studies, results, data and regulatory approvals, data (including from clinical studies), and filings, including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays and quality control and testing procedures, whether or not patented or patentable.

1.37 "**Knowledge of Seller**" or "**Seller's Knowledge**" or any other similar knowledge qualification, means the actual knowledge after reasonable investigation of Jay Kranzler, Lindsay Rosenwald or Lei Zheng.

1.38 "**Knowledge of Buyer**" or "**Buyer's Knowledge**" or any other similar knowledge qualification, means the actual knowledge after reasonable investigation of James Mackay, Ashwin Ram and BT Slingsby.

1.39 "**Laws**" means all laws, statutes, rules, regulations, ordinances, codes, consent agreement, requirement, constitution, treaty, writ, injunction, judgment, ruling, decree or order, in each case, having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.40 "**Liability**" means any direct or indirect liability, Indebtedness, commitment, expense, claim, deficiency, obligation, guaranty or endorsement of or by any Person of any type, whether asserted or unasserted, known or unknown, absolute or contingent, accrued or unaccrued, matured or unmatured, liquidated or unliquidated, due or to become due.

1.41 "**Lien**" means any lien, mortgage, pledge, encumbrance, charge, security interest or charge of any kind or nature whatsoever.

1.42 "**Liquidation Event**" means any bona fide, arms-length transaction (or series of related transactions) consisting of (a) the acquisition of the direct or indirect beneficial ownership of more than 50% of the then-outstanding capital stock or other voting securities of Buyer (including any surviving entity by merger, consolidation, conversion or otherwise) by a Third Party or a group of Third Parties, including by merger, consolidation, business combination or other transaction with such Third Party or Third Parties, pursuant to which the holders of direct or indirect beneficial ownership of more than 50% of the capital stock or other voting securities of Buyer immediately prior to such transaction cease to hold direct or indirect beneficial ownership of more than 50% of such outstanding capital stock or other voting securities, or otherwise cease to control Buyer (or, if applicable, such surviving entity), immediately following such transaction or series of related transactions, or (b) the sale, lease, transfer, exclusive license or other disposition by the Buyer or any subsidiary of the Buyer of all or substantially all the assets of the Buyer and its subsidiaries, taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Buyer if substantially all of the assets of the Buyer and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a direct or indirect wholly owned subsidiary of the Buyer; provided, however, that a Liquidation Event shall not include any transaction or series of related transactions principally for bona fide equity financing purposes in which cash is received by the Buyer or any successor or indebtedness of the Buyer is cancelled or converted or a combination thereof occurs.

1.43 "**MAA**" means a Marketing Authorization Application submitted to the European Medicines Agency ("**EMA**") for the applicable pharmaceutical product under the centralized European procedure for obtaining Regulatory Approval (excluding reimbursement decisions and/or price approvals) necessary and/or appropriate for the manufacture, production, distribution, marketing, sale and/or use of the pharmaceutical product for commercial purposes in the European Union.

1.44 "**NDA**" means a new drug application, submitted to the FDA pursuant to 21 U.S.C. § 355 seeking approval to market a new drug in the United States, and all supplements or amendments thereto.

1.45 "**Outstanding Notes**" means those certain convertible promissory notes issued by Buyer prior to the Closing in the aggregate principal amount of $[***].

1.46 "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications and rights to claim priority from any of such patents or applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (c) any and all patents that have issued

or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, design patents, certificates of invention, and unitary patents, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any patent term extensions, supplementary protection certificates, pediatric exclusivities, and the like) of the foregoing patents or patent applications ((a), (b), and (c)), and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.47 "**Patent Assignment**" means the Patent Assignment(s) evidencing the assignment by Seller and its Affiliates of the Purchased Patents, substantially in the form attached hereto as Exhibit C.

1.48 "**Permit**" means any approval, license, franchise, consent, approval, authorization, permission or waiver of, registration, declaration, exemption, permit, certificate, certificate of occupancy or order issued by any Governmental Authority.

1.49 "**Permitted Encumbrance**" means (a) statutory Liens for current Taxes not yet due and payable or the amount or validity of which is being contested in good faith by appropriate proceedings and for which appropriate reserves have been established in accordance with the Accounting Standards, (b) mechanics', materialmen's, carriers', workers', repairers' and similar statutory Liens arising or incurred in the ordinary course of business the existence of which do not or would not reasonably be expected to materially detract from the current value of, or materially interfere with, the present use of the Acquired Assets, and would not prevent, or be reasonably likely to prevent, Seller from performing its obligations hereunder, (c) Liens imposed by Law that do not or would not reasonably be expected to materially detract from the current value of, or materially interfere with, the present use of the Acquired Assets, and would not prevent, or be reasonably likely to prevent, Seller from performing its obligations hereunder and (d) matters set forth on Schedule 1.49.

1.50 "**Person**" means any individual, corporation, general or limited partnership, joint venture, limited liability company, estate, trust, association, other business or investment entity or unincorporated organization, or any Governmental Authority.

1.51 "**Post-Closing Tax Period**" means any Tax period beginning after the Closing Date and that portion of a Straddle Period beginning after the Closing Date.

1.52 "**Pre-Closing Tax Period**" means any Tax period ending on or before the Closing Date and that portion of any Straddle Period ending on the Closing Date.

1.53 "**Proceeding**" means any charge, dispute, action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Authority or any arbitrator or arbitration panel.

1.54 "**Property Taxes**" means all real property Taxes, personal property Taxes and similar ad valorem Taxes.

1.55 "**Purchased Deliverables**" means the items described on Exhibit D.

1.56 "**Purchased Intellectual Property**" means all Seller-Owned Intellectual Property.

1.57 "**Purchased Patents**" means the Patent(s) set forth in Schedule 1.57.

1.58 "**Purchase Option Price**" means the aggregate principal amount (which principal amount shall not exceed $6,357,023) and accrued, but unpaid interest calculated through the earlier of (i) March 31, 2025 or (ii) the initial closing of the Qualified Financing, under the Convertible Notes. For the avoidance of doubt, the Purchase

Option Price shall exclude any prepayment premium, default interest or any other fees, penalties or other amounts that are not attributable to principal and interest under such Convertible Notes.

1.59 "**Purchased Product**" means, as the context requires: (a) any pharmaceutical preparation, in any dosage form, formulation, presentation or package configuration containing or comprising, in part or in whole, the Compound, (b) any Licensed Product (as defined in the Fuji License Agreement), or (c) any raw materials, work-in-progress, packaging, supplies, parts, other inventories, and finished goods inventory containing or comprising the Compound to the extent in Seller's or any of its Affiliates' possession or control as of the Closing Date.

1.60 "**Qualified Financing**" means the next transaction (or series of related transaction) after the Closing in which Buyer issues and sells shares of its capital stock in exchange for aggregate gross proceeds of at least $120,000,000, including principal amounts converted pursuant to the Convertible Notes but excluding interest amounts converted pursuant to the Convertible Notes.

1.61 "**Registered Intellectual Property**" means all Intellectual Property Rights that are registered, filed, or issued under the authority of any Governmental Authority, including all patents, registered copyrights, registered trademarks and domain names and all applications for any of the foregoing.

1.62 "**Regulatory Approval**" means any approval, product and/or establishment licenses, registrations, or authorizations of any federal, state, or local regulatory agency, department, bureau, or other governmental entity, that is necessary for the commercial manufacture, use storage, import, export, transport, commercialization, and sale of a pharmaceutical product in a country in the Territory, including NDA, MAA, and pricing and national medical insurance program listings and applications, amendments, or supplements underlying any such procedures.

1.63 "**Regulatory Authority**" means any national, federal, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity whose review and/or approval is necessary for the manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of pharmaceutical or biological products in a given country or regulatory jurisdiction.

1.64 "**Regulatory Plan**" has the meaning ascribed to such term in the Stock Issuance Agreement.

1.65 **"Resolution Period End Date**" means the earlier to occur of (i) the one-year anniversary of the date that the Buyer receives minutes of the FDA Meeting, and (ii) the two-year anniversary of the Closing Date.

1.66 "**Royalty Agreement**" a royalty agreement between Buyer and Seller substantially in the form attached hereto as Exhibit E.

1.67 "**Sanctions**" means economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by (a) the U.S. government, including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or (b) the United Nations Security Council, the European Union, any European Union member state or His Majesty's Treasury of the United Kingdom.

1.68 "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.69 "**Security Agreement**" a security agreement between Buyer and Seller substantially in the form attached hereto as Exhibit F.

1.70 "**Seller Intellectual Property**" means all Seller-Owned Intellectual Property and Seller-Licensed Intellectual Property.

1.71 "**Seller Intellectual Property Licenses**" means any Contract under which (i) Seller or any of its Affiliates acquired or is authorized to use any Seller-Licensed Intellectual Property, or (ii) Seller or any of its Affiliates granted or is required to grant to any Person any right or license to make, have made, manufacture, use, sell, offer to sell, import, export, or otherwise distribute any Seller Intellectual Property, with or without the right to sublicense the same. For clarity, Seller Intellectual Property Licenses include the Fuji License Agreement.

1.72 "**Seller-Licensed Intellectual Property**" means all of Seller's rights to any Technology and Intellectual Property Rights owned by Third Parties that are specifically related to the Compound or the Purchased Product, including those set forth on Schedule 1.72.

1.73 "**Seller-Owned Intellectual Property**" means all Technology and Intellectual Property Rights owned or purported to be owned (whether exclusively, jointly or otherwise) by Seller that are specifically related to the Compound or the Purchased Product, including the Purchased Patents and those other Intellectual Property Rights set forth on Schedule 1.73.

1.74 "**Software**" means any computer program, operating system, database, applications system, firmware or software code of any nature, whether operational, under development or inactive, including all object code, source code, data files, processes, know-how, operating procedures, methods and all other Technology embodied with the foregoing, tools, developers' kits, utilities, developers' notes, technical manuals, user manuals and other documentation thereof, including comments and annotations related thereto, whether in machine-readable form, programming language or any other language or symbols and whether stored, encoded, recorded or written on disk, tape, film, memory device, paper or other media of any nature.

1.75 "**Stock Consideration**" means an aggregate number of shares of Common Stock of Buyer equal to 35% of Buyer's fully diluted capitalization immediately following the Closing, which is 1,000,000 shares of Common Stock of Buyer, and the incidental rights of such shares attached thereto pursuant to the Company's organizational documents, the Stock Issuance Agreement (including, for the avoidance of doubt, the "15% Anti-Dilution Right," as defined therein) or otherwise.

1.76 "**Stock Issuance Agreement**" means a stock issuance agreement between Buyer and Seller substantially in the form attached hereto as Exhibit G.

1.77 "**Straddle Period**" means any Tax period that begins on or before the Closing Date and ends after the Closing Date.

1.78 "**Tax**" or "**Taxes**" means any and all federal, state, local or foreign income, alternative or add-on minimum, gross income, gross receipts, accumulated earnings, sales, use, ad valorem, value added, transfer, franchise, profits, license, registration, recording, documentary, conveyancing, gains, withholding, payroll, employment, payroll, social security, national insurance, disability, unemployment, worker's compensation, excise, severance, stamp, occupation, premium, real property, personal property, environmental or windfall profit, custom duty, estimated or other tax, governmental fee in the nature of a tax or other like assessment or charge imposed by any Governmental Authority, including any interest, penalty, or addition thereto, whether or not disputed, and any obligation to indemnify or otherwise assume or succeed to the Tax Liability of any other Person by applicable Law, by contract or otherwise.

1.79 "**Tax Return**" means any return, report, declaration, claim for refund, information return or other document (including schedules thereto, other attachments thereto, amendments thereof, or any related or supporting information) relating to any Tax.

1.80 "**Technology**" means data, diagrams, inventions, methods and processes (whether or not patentable), algorithms, active pharmaceutical ingredients, mask works, network configurations and architectures, proprietary information, protocols, layout rules, schematics, packaging and other specifications, Software,

techniques, interfaces, verification tools, works of authorship, technical documentation, designs, test reports, routines, formulae, test vectors, IP cores, net lists, photomasks, processes, prototypes, samples, studies, and all other forms of technology.

1.81 "**Territory**" means the United States, the European Union (consisting of the countries in the European Union as of the date of the Second Amendment to the Fuji License Agreement), the United Kingdom, Canada, Algeria, Armenia, Azerbaijan, Bahrain, Djibouti, Egypt, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Malta, Morocco, Oman, Qatar, Saudi Arabia, Tunisia, Turkey, United Arab Emirates, West Bank and Yemen.

1.82 "**Third Party**" means any Person other than: (a) Buyer; (b) Seller; or (c) an Affiliate of the Parties.

1.83 "**Trade Secrets**" means all trade secrets, confidential unpatented or unpatentable inventions, invention disclosures, processes, formulae, developments, discoveries, technology, product formulations, manufacturing processes, data, standard operating procedures, cell lines, biological materials, compounds, probes, sequences, technical information, methods, biological materials, screening assays, bioassays, clones, molecules, protocols, reagents, experiments, lab results, or other confidential information, data or materials that in the reasonable business judgment of the owner thereof have value or confer a competitive advantage to such owner.

1.84 "**Transaction Documents**" means, collectively this Agreement, the Assignment and Assumption Agreement, the Bill of Sale, the Patent Assignment, the Voting Agreement, the Stock Issuance Agreement, the Royalty Agreement and the Security Agreement.

1.85 "**Voting Agreement**" means a voting agreement among Buyer, Seller and certain other parties thereto, substantially in the form attached hereto as Exhibit H.

1.86 **Additional Definitions**. Each of the following definitions is set forth in the Section indicated below:

| Definition | Section |
|---|---|
| "**Acquired Assets**" | 2.1 |
| "**Agreement**" | Preamble |
| "[***] **Data**" | 6.10 |
| "**Assumed Liabilities**" | 2.3 |
| "**Breach**" | 5.2(e)(x) |
| "**Buyer**" | Preamble |
| "**Buyer Cap**" | 7.3(c) |
| "**Buyer Indemnitees**" | 7.1(b) |
| "**Eisai Data**" | 6.10 |
| "**Seller Cap**" | 7.3(b) |
| "**Claims**" | 7.1(c) |
| "**Claim Notice**" | 7.1(c) |
| "**Closing Date**" | 4.1 |

| Definition | Section |
|---|---|
| "**Closing Date Payment**" | 3.2 |
| "**Closing Reimbursement Amount**" | 4.6 |
| "**Confidentiality Agreement**" | 6.6(c) |
| "**Deductible**" | 7.3(a) |
| "**Designated Parties**" | 5.2(j)(ii) |
| "**DPA**" | 5.2(j)(i) |
| "**Excluded Assets**" | 2.2 |
| "**Excluded Liabilities**" | 2.4 |
| "**FDA Application Integrity Policy**" | 5.2(h)(vi) |
| "**Indemnified Party**" | 7.1(c) |
| "**Indemnifying Party**" | 7.1(c) |
| "**Infringed**" | 5.2(e)(iv) |
| "**Later Identified Acquired Asset**" | 6.5(a) |
| "**Loss**" | 7.1(a) |
| "**Objection Date**" | 7.1(c) |
| "**Objection Notice**" | 7.1(c) |
| "**Option Exercise Notice**" | 8.1(a) |
| "**Party**" and "**Parties**" | Preamble |
| "**Pending Claim**" | 7.5(f) |
| "**Purchase Condition**" | 8.1(a) |
| "**Purchase Option**" | 8.1(a) |
| "**Purchase Option Closing**" | 8.1(b) |
| "**Purchase Price**" | 3.1 |
| "**Purchase Price Calculation**" | 6.4(c) |
| "**Receiving Party**" | 6.6(c) |
| "**Regulatory Permits**" | 5.2(h)(i) |
| **"Remaining Reimbursement Amount**" | 4.6 |
| "**Restricted Area**" | 6.7(a) |
| "**Restricted Business**" | 6.7(a) |

| Definition | Section |
|---|---|
| "**Restricted Countries**" | 5.2(j)(ii) |
| "**Restricted Period**" | 6.7(a) |
| "**Seller**" | Preamble |
| "**Seller Cap**" | 7.3(b) |
| "**Seller Indemnitees**" | 7.1(a) |
| "**Share Clawback**" | 7.5(a) |
| "**Transfer**" | 7.5(e) |
| "**Transfer Taxes**" | 4.4 |
| "**Upfront Expense Reimbursement Amount**" | 4.6 |

## 2. PURCHASE AND SALE

2.1 **Acquired Assets**. Subject to the terms and conditions contained in this Agreement and except as set forth in Section 2.2, at the Closing, Seller hereby sells, conveys, assigns, transfers and delivers to Buyer, and/or shall cause its Affiliates to sell, convey, assign, transfer and deliver to Buyer (to the extent applicable), and Buyer purchases and acquires, all rights, title and interest of Seller or its Affiliates, as applicable, in and to all of the assets, properties, interests, rights of every description, whether real, personal or mixed, tangible or intangible, owned or leased, used or otherwise employed by the Seller that are primarily related to the Compound or the Purchased Product (collectively, the "**Acquired Assets**"), in each case, free and clear of all Liens other than Permitted Encumbrances, which shall include:

(a) the Assumed Contracts, including all of the rights, title and interests of Seller or its Affiliates, as applicable, in the Assumed Contracts;

(b) the Compound, the Purchased Products and the rights, title and interests of Seller or its Affiliates, as applicable, in the same;

(c) the Purchased Deliverables;

(d) the Seller Intellectual Property;

(e) all Permits relating to or associated with the Purchased Deliverables, the Purchased Products or the Compound, in each case, to the extent transferable;

(f) all rights in and under all express or implied guarantees, warranties, representations, covenants, indemnities and similar rights in favor of Seller or its Affiliates, as applicable, and any claims against suppliers, insurers or other third parties, in each case, to the extent such rights are primarily related to the Purchased Products or the Compound;

(g) all goodwill relating to or associated with the Acquired Assets;

(h) all books and records or documents primarily relating to the Acquired Assets (other than Tax Returns);

(i) Tax Returns relating to non-income Taxes imposed on the Acquired Assets; and

(j) other assets specifically identified on Schedule 2.1.

2.2 **Excluded Assets**. Notwithstanding anything to the contrary in this Agreement, the Acquired Assets do not include, and Seller and its Affiliates, as applicable, shall not sell, convey, assign, transfer or deliver to Buyer, any assets other than the Acquired Assets, and, without limiting the generality of the foregoing, expressly exclude the following assets of Seller or its Affiliates (such assets being collectively referred to hereinafter as the "**Excluded Assets**"):

(a) all cash (including cash on hand and cash in transit), cash equivalents, bank accounts, bank deposits, marketable securities, corporate credit cards and other similar cash items of Seller and its Affiliates;

(b) all rights of Seller or its Affiliates arising under this Agreement, any Transaction Document or from the consummation of the transactions contemplated hereby or thereby, including all rights arising under any Excluded Liability;

(c) all rights to any refunds of Taxes paid by Seller (or for which Seller has made an indemnification payment hereunder) (or amounts credited against current cash Taxes otherwise due and payable in lieu of such a refund) with respect to any Pre-Closing Tax Period, excluding, for the avoidance of doubt, any Tax refunds or credits for Property Taxes that are allocable to any Post-Closing Tax Period pursuant to Section 6.4(b), and any other tax assets of Seller or its Affiliates for any taxable period;

(d) all of Seller's and its Affiliates intercompany account balances;

(e) all assets, tangible or intangible, wherever situated, not included in the Acquired Assets;

(f) all of Seller's corporate seals, organizational documents, minute books, stock books, records (in each case, other than those set forth in Sections 2.1(h) - (i)).

(g) any attorney-client privilege, rights under the work-product doctrine, and equivalent rights in jurisdictions outside of the United States of Seller as a result of legal counsel representing Seller in connection with the transactions contemplated by the Agreement and the Transaction Documents, and all files maintained by Seller in connection with the transactions contemplated by this Agreement and the Transaction Documents; and

(h) other specifically identified excluded assets set forth on Schedule 2.2.

2.3 **Assumed Liabilities**. Subject to the terms and conditions contained herein and except as otherwise provided in Section 2.4, at the Closing, Buyer will assume and pay, or perform and discharge when due, only the following Liabilities of Seller (such Liabilities, the "**Assumed Liabilities**"):

(a) any and all Liabilities relating to activities conducted by Buyer following the Closing with respect to the Acquired Assets, including the development, sale, manufacture or use of the Compound or Purchased Product;

(b) any and all Liabilities exclusively relating to the Dotinurad IND arising following the Closing;

(c) any Transfer Taxes required to be borne by Buyer pursuant to Section 4.4 and any Property Taxes to the extent specifically allocated to Buyer pursuant to Section 6.4(b);

(d) any and all liabilities and obligations arising under or relating to the Assumed Contracts, in each case, only to the extent any such liabilities or obligations shall have arisen out of, are related to or are in respect of, periods following the Closing;

(e) any and all liabilities for Taxes attributable to the Acquired Assets or the other Liabilities described in this Section 2.3, in each case, for or relating to any Post-Closing Tax Period;

(f) the Remaining Reimbursement Amount;

(g) other specifically identified assumed Liabilities set forth on Schedule 2.3.

2.4 **Excluded Liabilities**. Buyer will not assume or be responsible for any Liability or obligation of Seller or its Affiliates that is not specifically identified as an Assumed Liability under Section 2.3 (it being understood that Buyer is expressly disclaiming any express or implied assumption of any Liabilities other than the Assumed Liabilities), including any and all of the following (collectively, the "**Excluded Liabilities**"):

(a) all Liabilities and obligations of Seller or its Affiliates arising out of or relating to the Acquired Assets prior to the Closing;

(b) any Liabilities and obligations of Seller or its Affiliates arising under this Agreement or any Transaction Document;

(c) all Liabilities in respect of any Proceeding against Seller or its Affiliates (i) which shall have been asserted prior to the Closing or (ii) to the extent the basis of which shall have arisen out of, is related to or is in respect of periods prior to the Closing;

(d) any Liability and obligation of Seller and its Affiliates for any Indebtedness of any kind whatsoever;

(e) any Liability and obligation of Seller and its Affiliates for any intercompany account balances;

(f) any Excluded Taxes;

(g) any Liabilities and obligations arising out of or relating to the ownership of the Excluded Assets, whether arising before, on or after the Closing; and

(h) other specifically identified excluded Liabilities set forth on Schedule 2.4.

## 3. PURCHASE PRICE

3.1 **Purchase Price**. On the terms and subject to the conditions of this Agreement, the aggregate purchase price for the Acquired Assets and the Assumed Liabilities shall be an amount equal (a) to the aggregate fair market value as of the Closing Date of (i) the Stock Consideration (including any rights of Seller pursuant to the Stock Issuance Agreement related to the Stock Consideration) and (ii) the Purchase Option, *plus* (b) the Royalty Payments (as defined in the Royalty Agreement) paid to Seller pursuant to the Royalty Agreement (collectively, the "**Purchase Price**").

3.2 **Closing Date Payment**. At the Closing, on the terms and subject to the conditions of this Agreement and the Stock Issuance Agreement, Buyer shall issue the Stock Consideration to Seller (the "**Closing Date Payment**").

3.3 **Withholding Rights**. Buyer shall be entitled to deduct or withhold from any consideration payable or otherwise deliverable to Seller or any Affiliate of Seller or any other Person pursuant to this Agreement in such amounts as Buyer is required to deduct or withhold therefrom under the Code, or any applicable Law, with respect to the making of such payment; provided that Buyer shall notify Seller at least five Business Days prior to deducting and withholding from any amounts otherwise payable to Seller pursuant to this Agreement, which notice shall include the authority, basis and method of calculation for the proposed deduction or withholding, and shall use commercially reasonable efforts to cooperate with Seller to reduce or eliminate any such deduction or withholding. To the extent that such amounts are so deducted or withheld and, if applicable, paid to the appropriate Governmental

Authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction or withholding was made.

## 4. CLOSING AND POST-CLOSING MATTERS

4.1 **Closing Date**. The Closing hereunder will take place simultaneously with the execution of this Agreement (the "**Closing Date**") and will be effective for tax, accounting and other computational purposes as of 11:59 pm Pacific Time on the Closing Date. At the Closing, the Parties will exchange (or cause to be exchanged) documents by electronic exchange (including, with respect to documents, of portable document format (PDF) documents), or do, or cause to be done all things respectively required of each Party as specified in Section 4.2.

4.2 **Transactions at Closing**. At the Closing, subject to the terms and conditions hereof:

(a) **Seller's Actions and Deliveries**. Seller will deliver, or cause to be delivered, to Buyer or Buyer's Affiliates:

(i) an executed counterpart of the Agreement and executed counterparts of the other Transaction Documents to which Seller or its Affiliates are party;

(ii) the Acquired Assets; and,

(iii) a valid and duly executed IRS Form W-9 from Seller.

(b) **Buyer's Actions and Deliveries**. In consideration for the transfer of the Acquired Assets and the other transactions contemplated by this Agreement and the Transaction Documents, Buyer will deliver or cause to be delivered, to Seller or Seller's Affiliates:

(i) the Closing Date Payment;

(ii) an executed counterpart of this Agreement and executed counterparts of the other Transaction Documents to which Buyer or its Affiliates are party; and

(iii) within 10 Business Days following the Closing, the Closing Reimbursement Amount.

4.3 **Transfer.**

(a) At the Closing, subject to the terms and conditions hereof, Seller shall hereby pass and transfer the title of the Acquired Assets and Assumed Liabilities to Buyer and Seller is delivering to Buyer possession of such, and shall further deliver to Buyer proper assignments, conveyances and the Bill of Sale, the Assignment and Assumption Agreement and the Patent Assignment sufficient to convey to Buyer good and marketable title to effect or evidence transfers. Seller retains no rights or licenses to the Acquired Assets or Assumed Liabilities upon execution of this Agreement.

(b) Notwithstanding the foregoing, Seller will provide reasonable cooperation and assistance, as requested by the Buyer, in connection with the transfer of the Dotinurad IND to the Buyer and with the Buyer's preparation of all notices and documents required to be filed with or submitted to the FDA in order to transfer the Dotinurad IND to Buyer. Without limiting the foregoing and to the extent applicable: (i) Seller shall submit or file all documents and notices required to be submitted or filed by Seller, consistent with the process set forth in 21 C.F.R. part 314.72, or as may otherwise be required to transfer the Dotinurad IND to Buyer, (ii) the Buyer shall submit or file all documents and notices required to be submitted or filed by the Buyer, consistent with the process set forth 21 C.F.R. part 314.72, or as may be required to assume ownership of the Dotinurad IND, and (iii) to the extent not already provided prior to the Closing Date, Seller shall provide to Buyer an accurate

and complete copy of the Dotinurad IND, including without limitation, copies of all reports that are required to be submitted to the Dotinurad IND pursuant to the FDCA. Both Seller and Buyer agree to submit or file all such notices and documents it is required to submit pursuant to this Section 4.3(b) within the 10-day period immediately following the Closing.

(c) For a period of three months after the Closing, upon Buyer's request, Seller shall use commercially reasonable efforts to provide reasonable technical assistance to Buyer to enable Buyer to fully exploit the Acquired Assets, including assistance with understanding the nature and organization of the transferred Know-How. The Parties will agree on the format, timing, and scope of the foregoing assistance; provided, that no more than an aggregate of 50 hours of assistance will be provided by Seller or its Affiliates, as applicable, without cost reimbursement by Buyer.

4.4 **Transfer Taxes**. All transfer, sales, use, excise, stamp, conveyance, value added and other similar Taxes imposed with respect to the transfer of the Acquired Assets and any other transaction contemplated by this Agreement (such Taxes, "**Transfer Taxes**") shall be borne 50% by Seller and 50% by Buyer. The Party who is obligated by applicable Law to file any documents (including all Tax Returns) relating to Transfer Taxes shall use commercially reasonable efforts to prepare and file in a timely manner all such documents (subject to the other Party's review and comment), and, if required by applicable Law, the other Party will join in the execution of any such documents. The Party that paid such Transfer Taxes shall provide the other Party with evidence reasonably satisfactory to the other Party that such Transfer Taxes have been paid and the other Party shall reimburse the paying Party for its equal share of such Transfer Taxes within 10 days of receiving such evidence.

4.5 **Patent Registration**. Buyer will, at its responsibility and expenses, take all necessary steps and follow all procedures for the registration of the assignment of Purchased Patents. Seller will use reasonable efforts to cooperate with Buyer, at Buyer's expense, in connection with the registration of the assignment of Purchased Patents from Seller to Buyer.

4.6 **Upfront Expense Reimbursement**. At Closing, upon consummation of the transactions contemplated herein, Buyer shall (a) pay to Seller, in immediately available funds pursuant to written payment instructions delivered by Seller to Buyer, an amount of $613,515 (the "**Closing Reimbursement Amount**") as set forth on Schedule 4.6 and (b) assume certain costs set forth on Schedule 4.6 in an amount equal to $709,503 (the "**Remaining Reimbursement Amount**", and the sum of the Closing Reimbursement Amount and the Remaining Reimbursement Amount, the "**Upfront Expense Reimbursement Amount**"), in each case, on behalf of Seller or as reimbursement for certain expenses incurred by Seller related to the Acquired Assets to the extent actually paid by Seller on behalf of Buyer. The details regarding the Upfront Expense Reimbursement Amount are set forth on Schedule 4.6.

## 5. REPRESENTATIONS AND WARRANTIES

5.1 **Representations and Warranties of Buyer.** Buyer hereby represents and warrants to Seller, as of the Closing Date, as follows:

(a) **Organization**. Buyer is a Delaware corporation duly organized, validly existing and in good standing under the applicable Laws of Delaware. Buyer has all requisite corporate power and authority to own, lease and operate its properties and to carry on its business as is now being conducted.

(b) **Due Authorization; No Conflict**. Buyer has all necessary corporate power and authority to execute, deliver and perform its respective obligations under the Transaction Documents and to consummate the transactions contemplated therein, and the execution and delivery of the Transaction Documents and the performance of all of its respective obligations hereunder have

been duly authorized by Buyer. The signing, delivery and performance of this Agreement by Buyer is not prohibited by and will not (i) result in the breach of or a default under the constituent documents of Buyer; (ii) result in a material breach or material default under any material agreement or instrument binding on Buyer (other than any breach, default, violation or conflict that is reasonably likely to prevent Buyer from performing its obligations hereunder); or (iii) result in a material violation of any Law applicable to Buyer. This Agreement has been duly executed and delivered by Buyer and, assuming the due authorization, execution and delivery of this Agreement by Seller, constitutes the legal, valid and binding obligations of Buyer, enforceable against Buyer in accordance with its respective terms, except as enforceability may be limited or affected by applicable bankruptcy, insolvency, moratorium, reorganization or other laws of general application relating to or affecting creditors' rights generally.

(c) **Legal Proceedings**. There are no Proceedings pending or, to the Knowledge of Buyer, threatened against or by Buyer or any of its respective Affiliates that, if determined adversely to Buyer or its Affiliates, as applicable, would reasonably be expected to have a material adverse effect on Buyer's ability to consummate the transactions contemplated by this Agreement or the Transaction Documents.

(d) **Brokers**. No broker, investment banker, agent, finder or other intermediary acting on behalf of Buyer or under the authority of Buyer is or will be entitled to any broker's or finder's fee or any other commission or similar fee directly or indirectly in connection with any of the transactions contemplated hereby.

(e) **Funding**. Buyer has provided Seller true, correct and complete copies of each executed Outstanding Note and any amendments thereto and any other transaction documents entered into in connection therewith. Any Future Notes issued following the Closing will be on the same terms and conditions as the Outstanding Notes. As of the date hereof, Buyer has commenced discussions with potential investors in the Qualified Financing. Buyer is not aware of any fact or circumstance that would reasonably be expected to prevent Buyer from (i) developing a Regulatory Plan, (ii) to otherwise satisfy its obligations under this Agreement and the other Transaction Documents or (iii) consummating a Qualified Financing.

(f) **No Other Representations or Warranties**. Notwithstanding anything contained in this Agreement to the contrary, Buyer acknowledges that neither Seller, its Affiliates nor its or their representatives is making any representations or warranties whatsoever, directly or indirectly, express or implied, beyond those expressly given by Seller in Section 5.2, any Transaction Document or in any certificate or instrument delivered pursuant to this Agreement, including any representation or warranty regarding: the timing or substance of feedback from the FDA regarding any information submitted to the FDA in respect of the development of the Compound or Purchased Product; the likelihood or timing of submitting an NDA for the Compound to the FDA, the acceptance by the FDA of such NDA for the Compound and/or the approval by the FDA of such NDA for the Compound; or the timing of any decision by the FDA. Any claims Buyer may have for breach of representation or warranty shall be based solely on the representations and warranties of Seller set forth in Section 5.2, any Transaction Document or in any certificate or instrument delivered pursuant to this Agreement. Buyer acknowledges and agrees that there are inherent uncertainties in attempting to make forward-looking estimates, projections, forecasts and/or predictions with respect to the Acquired Assets, including the development of the Acquired Assets after the Closing, and that Buyer takes full responsibility for making its own evaluation of the adequacy and accuracy of any such forward-looking estimates, projections, or forecasts (including the reasonableness of the assumptions underlying any such estimates, projections, or forecasts). Buyer further

acknowledges that neither Seller nor any of its Affiliates, or its or their representatives, nor any other Person has made any representation or warranty, express or implied, as to the accuracy or completeness of any information regarding Seller not expressly set forth in this Agreement, any Transaction Document or in any certificate or instrument delivered pursuant to this Agreement.

(g) **Condition of Acquired Assets**. Buyer acknowledges and agrees that Buyer is acquiring the Acquired Assets without any representation or warranty as to the effectiveness or the success of the Acquired Assets, except as expressly set forth in Section 5.2 and the Disclosure Schedules. Buyer acknowledges and agrees that Seller, as of immediately prior to the Closing Date, has not undertaken any of the steps set forth in Schedule 5.1(g).

(h) **No Material Liabilities**. As of the date hereof, Buyer has no material Indebtedness or Liabilities, except for the Convertible Notes, any Indebtedness or Liabilities related to the transactions contemplated by the Transaction Documents and Liabilities occurring in the ordinary course of business.

5.2 **Representations and Warranties of Seller**. Seller hereby represents and warrants to Buyer, as of the Closing Date, and except as otherwise set forth on the Disclosure Schedule, as follows:

(a) **Organization**. Seller is a Delaware corporation duly organized, validly existing and in good standing under the applicable Laws of the State of Delaware. Seller has all requisite corporate power and authority to own, lease and operate its properties and to carry on its business as is now being conducted.

(b) **Due Authorization; No Conflict**. Seller has all necessary corporate power and authority to execute, deliver and perform its respective obligations under the Transaction Documents and to consummate the transactions contemplated therein, and the execution and delivery of this Agreement and the other Transaction Documents and the performance of all of its obligations hereunder and thereunder has been duly authorized by Seller. Seller is duly authorized and empowered to execute and deliver all the Transaction Documents to be executed by Seller. Except as set forth on Schedule 5.2(b)(i), the signing, delivery and performance of this Agreement by Seller is not prohibited by and will not (i) result in the breach of or a default under the constituent documents of Seller; (ii) result in the material breach of or a material default under any material agreement or instrument binding on Seller, including the Assumed Contracts; or (iii) result in a material violation of any Law applicable to Seller. This Agreement has been duly executed and delivered by Seller and, assuming the due authorization, execution and delivery of this Agreement by Buyer, constitutes the legal, valid and binding obligations of Seller, enforceable against Seller in accordance with its respective terms, except as enforceability may be limited or affected by applicable bankruptcy, insolvency, moratorium, reorganization or other laws of general application relating to or affecting creditors' rights generally. Except as set forth on Schedule 5.2(b)(ii), no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority or Third Party, on the part of Seller or its Affiliates, is required on connection with the execution, delivery and performance of this Agreement and the other Transaction Documents.

(c) **Acquired Assets.**

(i) Except for Seller Intellectual Property, the Seller has, and immediately prior to the Closing will have, good and valid title to, or a valid and binding leasehold interest or license in, all Acquired Assets, free and clear of any Liens except for Permitted Encumbrances. At the Closing, Seller will transfer to Buyer good and valid title to, or, if Seller has a leasehold

interest or license, a valid and binding leasehold interest or license in, all Acquired Assets, free and clear of any Liens except for Permitted Encumbrances. Except as set forth on Schedule 5.2(c), other than Seller, to the Knowledge of Seller, no other Person has any legal title to, or beneficial interest in, any of the Acquired Assets. Notwithstanding any other representations and warranties in this Agreement, the representations in Section 5.2(e) constitute the sole representations and warranties of the Company in this Agreement with respect to Seller Intellectual Property.

(ii) During the past three years, Seller has not been, and currently is not, in violation of any Law applicable to Seller or the Acquired Assets, which violation would be expected to materially detract from the value of or materially interfere with the current use of any of the Acquired Assets.

(iii) Except for the Excluded Assets and as set forth in Schedule 5.2(c)(iii), (A) neither the Seller nor, to the Knowledge of Seller, any Affiliate of Seller, is a party to any material Contract other than the Assumed Contracts, (B) nor does Seller have any current Liabilities under any material Contract (including any expired or terminated Contract), in each case, that is directly related to the Acquired Assets. Seller is not (and to Seller's Knowledge, no other party thereto is) in material breach or violation of, or default under any of the Assumed Contracts, and to Seller's Knowledge, no event has occurred and no circumstance or condition exists, which with or without notice or lapse of time, or both, would constitute a material breach or material default, or permit termination, modification, or acceleration, under any Assumed Contract or give any other Person the right to cancel, terminate, or modify any such Assumed Contract. Each Assumed Contract is valid, binding, enforceable and in full force and effect against Seller, and, to Seller's Knowledge, against the other party thereto, in each case in accordance with its terms (1) subject, as to enforcement, to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to creditor's rights generally or by equitable principles (whether considered in an action at law or in equity), and (2) except for such failures to be valid, binding or enforceable that would not individually or in the aggregate reasonably be expected to be material. To Seller's Knowledge, no event or circumstance has occurred that, with notice or lapse of time or both, would constitute an event of default under any Assumed Contract or result in a termination thereof or would cause or permit the acceleration or other changes of any right or obligation or the loss of any benefit thereunder. Seller has not received written notice of any pending material disputes and, to Seller's Knowledge, no material disputes have been threatened under any Assumed Contract included in the Acquired Assets. Except as set forth in Schedule 5.2(f)(ii), no Assumed Contract (x) limits or purports to limit the ability of Seller (or following the Closing, of Buyer) to compete in any line of business or with any Person in any geographic area or during any period of time, including any Contract that contains any non-competition, non-solicitation, non-hire or exclusivity restrictions, (y) contains any "most favored nation" rights or other preferential rights of any type or scope, including rights of first refusal or first offer, rights of first negotiation or any similar rights or provisions, (z) following the Closing, would create any joint venture, partnership or similar arrangement between Buyer and the applicable counterparty to such Contract.

(iv) The Acquired Assets constitute all of the tangible and intangible assets, property and rights owned, leased or licensed by Seller or its Affiliates with respect to the Compound. To the Knowledge of Seller, the Acquired Assets shall permit Buyer to continue to conduct the development, testing, safety and efficacy of the Compound following the Closing in all

respects in substantially the same manner as Seller or its Affiliates have conducted the same through the date hereof, it being acknowledged that Seller is not in possession of the Eisai Data or a development plan for the Compound that reflects the Eisai Data. Other than as set forth on Schedule 5.2(c)(iv), none of the Excluded Assets have been material to the foregoing.

(d) **Legal Proceedings**. There are no Proceedings pending or, to Seller's Knowledge, threatened against or by Seller or any of its Affiliates (a) relating to the Acquired Assets or the Assumed Liabilities or (b) that challenge or seek to prevent, enjoin or otherwise delay the transactions contemplated by this Agreement or the Transaction Documents. To Seller's Knowledge, there is no basis for any such Proceeding or action, suit, decree, arbitration, or investigation that could reasonably be expected to be material to the Acquired Assets. To Seller's Knowledge, there are no outstanding orders and no unsatisfied judgments, penalties, or awards against or affecting the Acquired Assets or the Assumed Liabilities.

(e) **Intellectual Property**.

(i) Schedule 5.2(e)(i) contains an accurate and complete list of (A) each item of Registered Intellectual Property included in the Seller Intellectual Property, (B) the jurisdiction in which such item of Registered Intellectual Property has been registered or filed and the applicable application, registration or serial number, and (C) all legal owner(s), co-owners and assignee(s) of record, as applicable.

(ii) To the Knowledge of Seller, Seller exclusively owns all right, title and interest in and to all of the Seller-Owned Intellectual Property, free and clear of any Liens, other than Permitted Encumbrances. To the Knowledge of Seller, no other Person purports to have any ownership interest in or other right to any such Seller-Owned Intellectual Property (including any interest or right in any derivatives thereof, whether or not developed as of the date hereof). Seller has not granted or agreed to grant to any other Person any exclusive rights in any Seller-Owned Intellectual Property. Seller has, and immediately prior to the Closing will have, as applicable, (x) good and valid title to, or a valid and binding leasehold interest in, or (y) a license for, all Seller Intellectual Property, free and clear of any Liens except for Permitted Encumbrances.

(iii) To the Knowledge of Seller, the Seller-Owned Intellectual Property, together with the Seller-Licensed Intellectual Property, constitutes all of the Technology and Intellectual Property Rights that are used or held for use by Seller or its Affiliates for Seller's current research, development, commercialization or other exploitation of the Compound or the Purchased Product in the Licensed Territory (as defined in the Fuji License Agreement). To the Knowledge of Seller, the Seller-Owned Intellectual Property, together with the Seller-Licensed Intellectual Property, constitutes all of the Technology and Intellectual Property Rights that are necessary for Buyer to continue to conduct the development, testing, safety and efficacy of the Compound following the Closing in all respects in substantially the same manner as Seller or its Affiliates have conducted the same through the date hereof, it being acknowledged that Seller is not in possession of the Eisai Data or a development plan for the Compound that reflects the Eisai Data.

(iv) To the Knowledge of Seller, the use of the Compound and the Purchased Product by Seller has not, within the past three years, infringed, misappropriated, interfered with or otherwise violated (collectively, "**Infringed**"), nor is Infringing, any Intellectual Property Right of any other Person, and, to the Knowledge of Seller, no claims of such Infringement has been

made or is pending or threatened in writing against Seller, or, to the Knowledge of Seller, any Affiliate of Seller. No Seller-Owned Intellectual Property, and to the Knowledge of Seller, no Seller-Licensed Intellectual Property, is subject to any Proceeding challenging the validity, ownership or enforceability of such Seller-Owned Intellectual Property or Seller-Licensed Intellectual Property, as applicable, except for office actions and other ex parte proceedings in the ordinary course of prosecuting or maintaining Registered Intellectual Property within the Seller Intellectual Property. Neither Seller nor, to the Knowledge of Seller, any Affiliate of Seller has received any written notice from any Third Party in the last three years challenging the validity, ownership or enforceability of any such Seller-Owned Intellectual Property, and to the Knowledge of Seller, the licensors of Seller-Licensed Intellectual Property have not received any written notice from any Third Party in the last three years challenging the validity, ownership or enforceability of any such Seller-Licensed Intellectual Property.

(v) Seller has taken all steps that are commercially reasonable to safeguard and maintain the confidentiality of all proprietary information that is Seller Intellectual Property. Without limiting the foregoing, to the Knowledge of Seller, there has been no misappropriation or public disclosure of any material confidential Seller Intellectual Property by any Person. To the Seller's Knowledge, each Person who is or was an employee, consultant or contractor of Seller and who has contributed to any of the Seller-Owned Intellectual Property that is within the Acquired Assets has executed a nondisclosure agreement applicable to Seller's confidential information and has executed agreements assigning to Seller such Person's rights to such Seller-Owned Intellectual Property, except for non-exclusive licenses to background Intellectual Property Rights granted to Seller or its Affiliates by employees, contractors and consultants in the course of providing services to Seller or its Affiliates. Without limiting the foregoing, to the Knowledge of Seller, no employee or independent contractor of Seller is in material default or material breach of any term of any employment agreement, nondisclosure agreement, assignment of invention agreement or similar agreement or contract relating in any way to the protection, ownership, development, use or transfer of the Seller-Owned Intellectual Property that is within the Acquired Assets.

(vi) To the Knowledge of Seller: (A) all Registered Intellectual Property within Seller Intellectual Property that has been issued or that has completed registration is valid and enforceable; and (B) no facts or circumstances exist that would invalidate (or render unenforceable) any Registered Intellectual Property that is Seller Intellectual Property that is pending issuance or registration. To the Knowledge of Seller, each item of such Registered Intellectual Property that is within the Acquired Assets has been duly maintained (including the payment of maintenance fees). Except as set forth on Schedule 5.2(e)(vi), no application related to such Registered Intellectual Property that is within the Acquired Assets has been abandoned or allowed to lapse, except for such Registered Intellectual Property that the Seller has permitted to abandon or lapse in its reasonable business judgment.

(vii) Neither Seller nor, to the Knowledge of Seller, any Affiliate of Seller is in material breach of any Seller Intellectual Property License, and neither Seller nor, to the Knowledge of Seller, any Affiliate of Seller has received any written notice of breach from such licensor.

(viii) To the Knowledge of Seller, neither the execution, delivery, or performance of this Agreement or any other Transaction Document, nor the consummation of any of the

transactions contemplated under this Agreement or any other Transaction Document will, with or without notice or the lapse of time, result in, or give any other Person the right or option to cause or declare, (A) a loss of rights in, or Lien (other than a Permitted Encumbrance) on, or the acceleration of any rights with respect to any Seller Intellectual Property that is within the Acquired Assets, (B) the release, disclosure, or delivery of any Seller-Owned Intellectual Property that is within the Acquired Assets by or to any escrow agent or other Person, or (C) the grant, assignment, or transfer to any other Person of any license or other right or interest under, to, or in any of Seller Intellectual Property that is within the Acquired Assets.

(ix) To the Seller's Knowledge, except as stated in patents and patent applications of the Registered Intellectual Property within the Acquired Assets that a particular invention was made with government support awarded by a federal agency, no funding, facilities, or personnel of any Governmental Authority were used to develop any Seller-Owned Intellectual Property, or, to Seller's Knowledge, any Seller-Licensed Intellectual Property.

(x) Seller is and at all times since January 1, 2021 has been, in material compliance with all applicable Data Protection Requirements. Seller has implemented and maintained commercially reasonable technical, physical, organizational, and administrative measures and policies to protect the IT Systems and data against unauthorized access, use, modification, disclosure, or loss (each, a "**Breach**"), including, without limitation, reasonable backup, security and disaster recovery technology and procedures, and have timely and reasonably remediated any audit findings relating to their security safeguards. Since January 1, 2021, no written notices have been received by, and no written claims, charges or complaints have been made against, Seller by any Person alleging a violation of any Data Protection Requirements. The IT Systems are free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants, and there have not been any Breaches since January 1, 2021. To Seller's Knowledge, the transactions contemplated by this Agreement will not result in any liabilities in connection with any Data Protection Requirements.

(f) **Tax Matters**.

(i) All material Tax Returns that were required to be filed with respect to the Acquired Assets have been duly and timely filed with the appropriate Governmental Authorities. All such Tax Returns are complete and accurate in all material respects. All material Taxes due and owing with respect to the Acquired Assets (whether or not shown on any Tax Return) have been timely paid. There are no liens on any of the Acquired Assets for Taxes (other than Permitted Encumbrances).

(ii) No deficiencies for Taxes with respect to the Acquired Assets have been claimed, proposed or assessed by any Governmental Authority. There are no pending audits, investigations, disputes, notices of deficiency, claims or other actions for or relating to any Liability for Taxes with respect to the Acquired Assets, and none has been proposed in writing. There are no matters under discussion with any Governmental Authority relating to Taxes with respect to the Acquired Assets that are likely to result in an additional Liability for Taxes with respect to Buyer. Seller (or any predecessor thereof) has not waived any statute of limitations in respect of Taxes or agreed to any extension of time with respect to a Tax assessment or deficiency, in each case, with respect to the Acquired Assets.

(iii) Seller has complied in all material respects with its obligations to timely withhold and pay all Taxes required to have been withheld and paid in connection with amounts paid or owing to any current or former employee, service provider, creditor, stockholder or other Person, in each case, to the extent the failure to do so would give rise to a Lien on the Acquired Assets.

(g) **Compliance with Laws**. Seller is in material compliance, and at all times since January 1, 2021 has been in material compliance, with all applicable Laws relating to the Acquired Assets. No written notices have been received by, and, to the Knowledge of Seller, no claims have been filed against, Seller alleging a violation of any applicable Laws relating to the Acquired Assets.

(h) **Regulatory Matters.**

(i) With respect to the Purchased Product, the Seller is and, and to the Knowledge of Seller, their respective directors, officers, employees, and agents have at all times since January 1, 2021 been, in material compliance with all Healthcare Laws presently applicable to the development, testing, manufacture, adverse event reporting, safety, efficacy, import or export of the Compound. Seller has not had any manufacturing site (whether owned by a Seller or that of a contract manufacturer) for the Purchased Product, subject to a Governmental Authority shutdown or import or export prohibition, nor has the Seller received any FDA Form-483 or other Governmental Authority notice of inspectional observations, "warning letters," "untitled letters" with respect to the Compound, or requests or requirements to make changes to the Compound, nor has Seller or, to Seller's Knowledge, its Affiliates received any similar correspondence or notice from the FDA or other Governmental Authority entity alleging or asserting material noncompliance with any applicable Healthcare Law with respect to the Compound or Regulatory Permit, and, to the Seller's Knowledge, neither the FDA nor any other governmental entity has threatened such action.

(ii) Seller possesses, and is in material compliance with the terms of, all such Permits from the appropriate federal, state or foreign regulatory authorities, including without limitation, the FDA or any other federal, state or foreign agencies or bodies engaged in the regulation of drugs and other pharmaceutical products, currently necessary for the development, testing, reporting, import or export of the Compound (collectively "**Regulatory Permits**"). All such Regulatory Permits are valid and in full force and effect, and Seller has not received any written notice of proceedings relating to the suspension, adverse modification, revocation or cancellation of any such Regulatory Permit. Seller has fulfilled and performed all of its material obligations with respect to the Regulatory Permits, no event has occurred which allows, or after notice or lapse of time would reasonably be expected to allow, revocation, termination or material impairment of the rights of Seller of any Regulatory Permit.

(iii) Since January 1, 2021, all applications, notifications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom, utilized as the basis for or submitted in connection with any and all requests for a Regulatory Permit from the FDA or other Governmental Authority relating to the Compound, when submitted to the FDA or other Governmental Authority were, to the Knowledge of Seller, true, complete and correct in all material respects as of the date of submission and/or any necessary or required updates, changes, corrections or modifications to such applications, submissions,

information and data have been submitted to the FDA or such other Governmental Authority.

(iv) Neither Seller, nor, any officer, employee or, to Seller's Knowledge, any agent or contractor of Seller has been convicted of any crime or engaged in any conduct that has previously caused or would reasonably be expected to result in (i) debarment by the FDA under 21 U.S.C. Sections 335a, or disqualification under any similar law, rule or regulation enforced by any other governmental entity, (ii) debarment, suspension, or exclusion under any federal healthcare programs or by the General Services Administration, or (iii) exclusion under 42 U.S.C. Section 1320a-7 or any similar law, rule or regulation of any comparable governmental entities.

(v) Neither Seller nor, any Affiliate of Seller is not a party to any corporate integrity agreements, monitoring agreements, deferred or non-prosecution agreements, consent decrees, settlement orders, or similar agreements with or imposed by any Governmental Authority.

(vi) Neither Seller, nor any of its officers, employees, or, to the Knowledge of Seller, any of its contractors or agents, is the subject of any pending or, to the Seller's Knowledge, threatened investigation by FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" policy as stated at 56 Fed. Reg. 46191 (September 10, 1991) (the "**FDA Application Integrity Policy**") and any amendments thereto, or by any other similar governmental entity pursuant to any similar policy. Neither Seller, nor any of its officers, employees, or, to Seller's Knowledge, any contractors or agents (when acting in such capacity) has made any materially false statements on, or material omissions from, any notifications, applications, approvals, reports and other submissions made to FDA or any similar governmental entity with respect to the Compound that would reasonably be expected to provide a basis for FDA to invoke the FDA Application Integrity Policy or for any similar governmental entity to invoke a similar policy.

(vii) The clinical, pre-clinical and other studies, tests and trials conducted by or on behalf of or sponsored by Seller, or in which Seller has participated, in each case with respect to the Compound were and, if still pending, are being conducted in all material respects in accordance with all applicable laws, rules, protocols, procedures and regulations to which they are subject, including without limitation, the FDCA and its implementing regulations codified at 21 C.F.R. parts 50, 54, 56, 58, and 312. No investigational new drug application submitted by or on behalf of Seller to the FDA or to any comparable Governmental Authority with respect to the Compound has been terminated or suspended by the FDA or such other comparable Governmental Authority, and neither the FDA nor any comparable Governmental Authority has commenced, or, to the Seller's Knowledge, threatened to initiate, any action to place a clinical hold order on, or otherwise terminate, adversely modify, delay or suspend, any proposed or ongoing clinical investigation conducted or proposed to be conducted by or on behalf of Seller with respect to the Compound.

(i) **Power of Attorney**. There are no outstanding powers of attorney executed by or on behalf of Seller or its Affiliates in respect of the Acquired Assets, including the Purchased Product in the Territory.

(j) **DPA; Sanctions**.

(i) Seller is not a "foreign person" or a "foreign entity," as defined in Section 721 of the Defense Production Act, as amended, including all implementing regulations thereof (the

"**DPA**"). Seller is not controlled by a "foreign person," as defined in the DPA. Seller does not permit any foreign person affiliated with Seller, whether affiliated as a limited partner or otherwise, to obtain through Seller any of the following with respect to Buyer: (i) access to any "material nonpublic technical information" (as defined in the DPA) in the possession of Buyer; (ii) membership or observer rights on the Board of Directors or equivalent governing body of Buyer or the right to nominate an individual to a position on the Board of Directors or equivalent governing body of Buyer; (iii) any involvement, other than through the voting of shares, in the substantive decision-making of Buyer regarding (x) the use, development, acquisition, or release of any "critical technology" (as defined in the DPA), (y) the use, development, acquisition, safekeeping, or release of "sensitive personal data" (as defined in the DPA) of U.S. citizens maintained or collected by Buyer, or (z) the management, operation, manufacture, or supply of "covered investment critical infrastructure" (as defined in the DPA); or (iv) "control" of Buyer (as defined in the DPA).

(ii) Neither Seller, nor any of its officers, directors, employees, agents, stockholders or partners, is (A) organized under the laws of, ordinarily resident in, or located in a country or territory that is the subject of comprehensive Laws and regulations pertaining to Sanctions administered by the United States (which as of the date of this Agreement comprise Crimea region of Ukraine, the non-government controlled areas of Zaporizhzhia and Kherson Regions of Ukraine, the so-called Donetsk People's Republic of Ukraine, the so-called Luhansk People's Republic of Ukraine, Cuba, Iran, North Korea, and Syria ("**Restricted Countries**")); (B) the government of a Restricted Country or the Government of Venezuela; (C) designated on a Sanctions-related list of designated Persons maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, the United Nations Security Council, the European Union, any Member State of the European Union, or the United Kingdom; or (D) 50% or more owned or, where relevant under applicable Sanctions, controlled, individually or in the aggregate, by one or more such Person or Persons (collectively, "**Designated Parties**"). In the past five years, the Seller and its officers, directors, employees, agents, stockholders or partners has (x) complied with all applicable Sanctions and Export Control Laws; (y) not been the subject of or otherwise involved in investigations or enforcement actions by any Governmental Authority or other legal proceedings with respect to any actual or alleged violations of Sanctions or Export Control Laws, and has not been notified of any such pending or threatened actions. In the past five years, the Seller has not operated in or engaged in any activities or business, direct or indirect, with or involving any Restricted Country or Designated Party.

(k) **Complete Copies of Materials**. To the Knowledge of Seller, each material document relating to the Acquired Assets has been made available to Buyer (or made available in an electronic "data room" for review by Buyer), and in each case, each applicable document is a true and complete copy of each such document in all material respects. Seller has provided Buyer with true, complete and correct copies (including all modifications, amendments, extensions and supplements thereto and waivers thereunder) of all Assumed Contracts. In each case where a representation and warranty of Seller in this Agreement requires the listing of documents and agreements, a true and complete copy of all such documents and agreements have been made available to Buyer (or made available in an electronic "data room" for review by Buyer).

(l) **Broker**. No broker, investment banker, agent, finder or other intermediary acting on behalf of Seller or under the authority of Seller is or will be entitled to any broker's or finder's fee or any other

commission or similar fee directly or indirectly in connection with any of the transactions contemplated hereby.

(m) **No Other Representations or Warranties**. Notwithstanding anything contained in this Agreement to the contrary, Seller acknowledges that neither Buyer, its Affiliates nor its or their representatives is making any representations or warranties whatsoever, directly or indirectly, express or implied, beyond those expressly given by Buyer in Section 5.1, any Transaction Document or in any certificate or instrument delivered pursuant to this Agreement. Any claims Seller may have for breach of representation or warranty shall be based solely on the representations and warranties of Seller set forth in Section 5.1, any Transaction Document or in any certificate or instrument delivered pursuant to this Agreement. Seller acknowledges and agrees that there are inherent uncertainties in attempting to make forward-looking estimates, projections, forecasts and/or predictions with respect to the Acquired Assets, including the development of the Acquired Assets after the Closing, and that Seller takes full responsibility for making its own evaluation of the adequacy and accuracy of any such forward-looking estimates, projections, or forecasts (including the reasonableness of the assumptions underlying any such estimates, projections, or forecasts). Seller further acknowledges that neither Buyer nor any of its Affiliates, or its or their representatives, nor any other Person has made any representation or warranty, express or implied, as to the accuracy or completeness of any information regarding Buyer not expressly set forth in this Agreement, any Transaction Document or in any certificate or instrument delivered pursuant to this Agreement.

(n) **DISCLAIMER OF CERTAIN REPRESENTATIONS AND WARRANTIES**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS SECTION 5.2, ANY OTHER TRANSACTION DOCUMENT OR IN ANY CERTIFICATE OR INSTRUMENT DELIVERED BY OR ON BEHALF OF SELLER PURSUANT TO THIS AGREEMENT, SELLER EXPRESSLY DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND OR NATURE, WHETHER STATUTORY, EXPRESS, OR IMPLIED, INCLUDING AS TO THE CONDITION, FUTURE PROSPECTS, FORWARD LOOKING STATEMENTS, VALUE, QUALITY OF THE ACQUIRED ASSETS, MERCHANTABILITY, SUITABILITY, OR FITNESS FOR ANY PARTICULAR PURPOSE, NON INFRINGEMENT OF THIRD PARTY RIGHTS OR ARISING FROM ANY COURSE OF DEALING, USAGE OR TRADE PRACTICES.

## 6. COVENANTS

6.1 **Diligence Obligations Owed to Seller; Buyer Restrictions**.

(a) From and after the Closing, (a) Buyer shall use Commercially Reasonable Efforts to develop, obtain Regulatory Approval for, and commercialize a pharmaceutical product in any dosage or form or formulation that contains or comprises the Compound and/or constitutes a Licensed Product (as defined in the Fuji License Agreement), (b) for a period commencing on the date of this Agreement and ending on the earlier of (i) such time as Buyer or any of its Affiliates has submitted an NDA for the Compound with the FDA for the purpose of obtaining approval for a pharmaceutical product in any dosage or form or formulation that contains or comprises the Compound and/or constitutes a Licensed Product (as defined in the Fuji License Agreement) or (ii) the date on which the Board of Directors of Buyer determines in good faith to discontinue the development of the Compound (including the consent of the Urica Director (as defined in the Voting Agreement)), Buyer shall not, without the written consent of Seller, research or develop, or obtain control, whether through acquisition or otherwise, directly or indirectly, of any URAT1 inhibitor related to gout other than the Compound, and (c) Buyer shall not amend or waive the terms and conditions of the Convertible

Notes to increase the applicable interest rate applicable to such Convertible Notes or in any other manner that would materially and adversely affect or increase any of Seller's rights or obligations under any Transaction Document. For purposes of this Section 6.1, "Commercially Reasonable Efforts" shall have the meaning set forth in the Fuji License Agreement as currently in effect.

(b) Buyer currently intends, and will make good faith efforts, to take the actions set forth on Schedule 6.1(b) in accordance with the time frames set forth in Schedule 6.1; provided, that, to the extent Buyer does not achieve, satisfy or complete the actions set forth in Schedule 6.1 in accordance with the time frames set forth therein, unless Buyer's actions or omissions related to the pursuit of the actions set forth on Schedule 6.1(b) involve Fraud by Buyer, any failure related to this Section 6.1(b) shall not constitute a breach of this Section 6.1(b).

6.2 **Further Assurances**. After the Closing, upon the terms and subject to the conditions contained herein, the Parties agree to execute any documents, instruments or conveyances of any kind which may be reasonably necessary or advisable to carry out any of the transactions contemplated by this Agreement or the Transaction Documents, and to cooperate with each other in connection with the foregoing, including to vest Buyer or its designee with full right, title and possession to the Acquired Assets.

6.3 **Access and Assistance**. At any time or from time to time after the Closing, if a Party is contesting or defending against any Proceeding relating to (a) any transaction contemplated by this Agreement or the Transaction Documents or (b) any fact, situation, condition, event, action, failure to act, or transaction occurring prior to the Closing Date involving the Acquired Assets or the Assumed Liabilities, upon such Party's written request, the other party hereto shall (i) reasonably cooperate with the contesting or defending party and its counsel in, and assist the contesting or defending party and its counsel with, the contest or defense, (ii) make available such other Party's personnel (including for purposes of fact finding, consultation, interviews, depositions, and, if required, as witnesses), and (iii) provide such information, testimony, and access to its books and records, in each case, as shall be reasonably requested in connection with the contest or defense, all at the sole cost and expense of the contesting or defending party; provided, however, that the foregoing shall not apply to any matter for which the contesting or defending party is seeking indemnification under Article 7 or involving a dispute between or among the Parties or their respective Affiliates.

6.4 **Tax Matters**.

(a) Each Party shall use commercially reasonable efforts to cooperate in furnishing such information and assistance relating to the Acquired Assets to the extent reasonably requested by the other Party in connection with the filing of Tax Returns, the making of any election relating to Taxes, the preparation for any audit by any taxing authority and the prosecution or defense of any claim, suit or Proceeding relating to any Tax. Each of Buyer and Seller shall retain all books and records with respect to Taxes pertaining to the Acquired Assets for a period of at least seven years following the Closing Date. Buyer and Seller shall cooperate fully with each other in the conduct of any audit, litigation or other Proceeding relating to Taxes involving the Acquired Assets. Seller shall promptly notify Buyer in writing upon receipt by Seller of notice of any pending or threatened Tax audits or assessments relating to the income, properties or operations of Seller that reasonably may be expected to relate to or give rise to a lien on the Acquired Assets.

(b) To the extent not otherwise provided in this Agreement, Seller shall be responsible for and shall promptly pay when due all Property Taxes levied with respect to the Acquired Assets attributable to the Pre-Closing Tax Period. All Property Taxes levied with respect to the Acquired Assets for the Straddle Period shall be apportioned between Buyer and Seller based on the number of days of such Straddle Period included in the Pre-Closing Tax Period and the number of days of such Straddle Period included in the Post-Closing Tax Period. Seller shall be liable for the proportionate

amount of such Property Taxes that is attributable to the Pre-Closing Tax Period, and Buyer shall be liable for the proportionate amount of such Property Taxes that is attributable to the Post-Closing Tax Period. Upon receipt of any bill for such Property Taxes, Buyer or Seller, as applicable, shall present a statement to the other setting forth the amount of reimbursement to which each is entitled under this Section 6.4(b) together with such supporting evidence as is reasonably necessary to calculate the proration amount. The proration amount shall be paid by the Party owing it to the other within 10 days after delivery of such statement. In the event that Buyer or Seller makes any payment for which it is entitled to reimbursement under this Section 6.4(b), the applicable Party shall make such reimbursement promptly but in no event later than 10 days after the presentation of a statement setting forth the amount of reimbursement to which the presenting Party is entitled along with such supporting evidence as is reasonably necessary to calculate the amount of reimbursement.

(c) **Purchase Price Allocation**. The Parties agree that, for U.S. federal and applicable state and local income Tax purposes, the Purchase Price, the Assumed Liabilities (to the extent properly taken into account under the Code) and any other amounts treated as consideration for applicable Tax purposes shall be allocated among the Acquired Assets in accordance with Section 1060 of the Code (the "Purchase Price Allocation"). Buyer shall, as soon as reasonably practical (but in any event within 75 days after the Closing) propose a calculation of the Purchase Price (which, for the avoidance of doubt, shall be determined consistent with Section 3.1) (the "Purchase Price Calculation") and a draft Purchase Price Allocation to Seller. Seller and Buyer shall negotiate in good faith and shall use their reasonable efforts to agree upon the Purchase Price Calculation and the Purchase Price Allocation. If Seller and Buyer are unable to resolve any dispute with respect to the Purchase Price Calculation or the Purchase Price Allocation within 30 days after the delivery of the Purchase Price Calculation and draft Purchase Price Allocation to Seller, such dispute shall be resolved by the Independent Accountant, with fees and expenses of the Independent Accountant borne in inverse proportion as they may prevail such that the Party with whom the Independent Accountant more closely agrees pays a lesser portion of such fees and expenses and the other Party pays a greater portion. If the Purchase Price is adjusted pursuant to Section 6.4(d) or as a result of additional Royalty Payments (as defined in the Royalty Agreement) paid to Seller pursuant to the Royalty Agreement, the Purchase Price Calculation and the Purchase Price Allocation shall be updated in a manner consistent with this Section 6.4(c). Seller and Buyer agree to file their respective Tax Returns in accordance with the Purchase Price Calculation and the Purchase Price Allocation.

(d) Notwithstanding anything to the contrary in this Agreement, (i) for income Tax purposes, any payments pursuant to Article 7 shall be treated as an adjustment to the consideration paid to Seller for the Acquired Assets to the fullest extent permitted by applicable Law, and (ii) neither Buyer nor Seller shall have any obligation to provide (or to provide access to) any income Tax Return filed or prepared on a consolidated, unitary, or combined basis and that includes Buyer or Seller, as applicable, for any period.

6.5 **Wrong Pockets**.

(a) If at any time after the Closing, either Seller or Buyer in good faith identifies any asset properly transferable as an Acquired Asset that was not included in the Acquired Assets transferred at the Closing (any such asset, a "**Later Identified Acquired Asset**"), then Buyer or Seller, as applicable, shall provide written notice to the other party identifying such Later Identified Acquired Asset. Promptly following delivery of such written notice, Seller shall, or shall cause its Affiliates to, transfer such Acquired Asset(s) as soon as reasonably practicable to Buyer or its designee for no consideration (it being acknowledged and agreed that Buyer shall have already paid good consideration for all Acquired Assets by paying the Closing Date Payment at Closing). A Party

shall notify the other Party as soon as reasonably practicable upon becoming aware that there are any Acquired Assets in its possession or control or that should have been transferred at the Closing, as applicable.

(b) If at any time after the Closing, either Seller or Buyer in good faith identifies any Excluded Asset that was improperly or inadvertently transferred to Buyer or its designated Affiliates, then Buyer or Seller, as applicable, shall provide written notice to the other Party identifying such Excluded Asset. Promptly following delivery of such written notice, Buyer shall transfer such Excluded Asset as soon as reasonably practicable to Seller or its designee for no consideration (it being acknowledged and agreed that the parties have not agreed to sell such Excluded Asset). A Party shall notify the other Party as soon as reasonably practicable upon becoming aware that there are any Excluded Assets in its possession or control or that were improperly or inadvertently transferred at Closing, as applicable.

6.6 **Confidentiality**. From and after the Closing Date:

(a) Seller shall hold, and shall cause its Affiliates, and their respective officers, directors, managers, employees and agents to hold, in strict confidence from any Person and not use for their own benefit, (i) all documents and information concerning Buyer, or any of Buyer's Affiliates provided to it by Buyer or Buyer's officers, directors, managers, agents or Affiliates in connection with this Agreement, (ii) the terms and conditions of this Agreement, and (iii) all documents and information concerning or within the Acquired Assets.

(b) Buyer shall hold, and shall cause its Affiliates, and their respective officers, directors, employees and agents to hold, in strict confidence from any Person and not use for their own benefit, (i) all documents and information concerning Seller or any of its Affiliates provided to it by Seller or its officers, directors, managers, agents or Affiliates, in connection with this Agreement, and (ii) the terms and conditions of this Agreement; provided, however, except as required by applicable Law, that the foregoing restrictions shall not apply after Closing to Buyer's or any of its Affiliates' and their respective officers', directors', employees' and agents' use or disclosure of (A) documents and information concerning or within the Acquired Assets, (B) any information developed by or on behalf of Buyer or any of its Affiliates, without reference to any of document or information described in the foregoing clause (i) and that is not concerning or within the Acquired Assets, or (C) to the extent Buyer has entered into a confidentiality agreement with such Person prior to any discussions or disclosure of the terms and conditions of this Agreement.

(c) Notwithstanding anything to the contrary herein, the covenants set forth in this Section 6.6 shall not apply to the disclosure of any documents or information by a Party (the "**Receiving Party**") to the extent: (i) such Party is compelled to disclose such documents or information by judicial or administrative process or by other requirements of applicable Law, (ii) such documents or information are disclosed in an action brought by a Party in pursuit of its rights or in the exercise of its remedies under this Agreement or the Transaction Documents, (iii) such Party or its Affiliates discloses such documents or information in connection with the public reporting requirements of applicable securities laws and/or stock exchanges, or (iv) such documents or information can be shown to have been (A) previously known by the Receiving Party (other than any documents and information concerning or within the Acquired Assets in the case of Seller as the Receiving Party), (B) in the public domain (either prior to or after the furnishing of such documents or information hereby) through no fault of such Receiving Party or (C) later acquired by the Receiving Party from another source if, to the knowledge of the Receiving Party after reasonable inquiry, such source is not under an obligation to keep such documents and information confidential. Notwithstanding the

foregoing, in the event the Receiving Party is required to make a disclosure pursuant to the foregoing clause (i) or (ii), to the extent practicable and not prohibited by law, it shall (1) give reasonable advance notice to the other Party of such disclosure, (2) provide the other Party with the reasonable opportunity to secure confidential treatment of such documents or information to be disclosed (at such other Party's request and expense), (3) reasonably cooperate with any such efforts by the other Party (at such other Party's request and expense) to secure confidential treatment of such documents or information, and (4) disclose only such minimal portion of the documents or information as is, on the advice of counsel, required to be disclosed. Disclosure by the Receiving Party of documents or information in accordance with any of the foregoing provisions of this Section 6.6 shall not, in and of itself, cause the information so disclosed to cease to be subject to the non-disclosure and non-use obligations under this Section 6.6, except to the extent that, by virtue of disclosure by the Receiving Party in full compliance with this Section 6.6, such information becomes generally known or available. Nothing herein shall prohibit a Party from disclosing documents and information covered by this Section 6.6 to its or their representatives who are receiving such documents or information for the purpose of the performance of obligations or exercise of rights under this Agreement, including any indemnification matter under Article 7 or involving dispute between or among the Parties or their respective Affiliates, so long as such representative has been instructed that such documents or information are subject to the confidentiality obligations set forth in this Section 6.6 and is bound either by contract, employment policies, fiduciary or professional ethical obligation to maintain such documents or information in confidence and the Party disclosing such documents or information shall be responsible for any failure by such representatives which, if committed by such Party, would be a breach of this Agreement. The Confidentiality Agreement between Seller and [***], dated April 11, 2023 (the "**Confidentiality Agreement**") will continue to apply through the Closing (at which time it shall automatically terminate and be of no further force and effect). Each Party will be permitted to retain (but not use) one file copy of all confidential information on a confidential basis to evidence the scope of and to enforce the Party's obligation of confidentiality and all back-up electronic media maintained in the ordinary course of business for archival purposes; provided, however, that, notwithstanding anything to the contrary herein, the confidentiality obligations herein continue for as long as a Party retains any such confidential information.

6.7 **Non-Competition; Non-Solicit**.

(a) For a period (the "**Restricted Period**") commencing on the date of this Agreement and ending on the earliest of (i) the three-year anniversary of the Closing Date, (ii) upon any breach by Buyer of, or any failure by Buyer to perform, the covenants or agreements set forth in (A) Section 6.1(a), Section 8.1, Section 8.2(i), Section 8.2(ii), and Section 8.2(iii) (B) the Stock Issuance Agreement, (C) the Royalty Agreement or (D) the Security Agreement; provided, that this Section 6.7(a)(ii) shall only become effective after Seller notifies Buyer in accordance with Section 9.2 of any purported breach or failure to perform in accordance with clauses (A)-(D) of this subsection, and Buyer shall fail to cure such breach or failure to perform for a period of 30 Business Days after receipt by Buyer of notice of such breach or failure to perform delivered by Seller, (iii) the exercise by Seller of the Purchase Option pursuant to Section 8.1, or (iv) such time as Buyer or any of its Affiliates cease to conduct researching, developing, designing, formulating, producing, marketing, distributing and selling, by themselves or through Third Parties, a URAT1 inhibitor related to gout (the "**Restricted Business**"), Seller shall not, and shall not permit any of its Affiliates to, at any time during the Restricted Period, and except with the written consent of Buyer, which consent may not be unreasonably withheld, conditioned or delayed, directly or indirectly, either for Seller, its Affiliates or in collaboration with any other Person, participate in, engage in, have any equity interest in, or manage any person, firm, corporation, partnership or business (whether as director,

officer, employee, agent, representative, partner, security holder, consultant or otherwise), with or without pay, that engages in the Restricted Business or competes with any portion of the Restricted Business or the Acquired Assets anywhere in the world (the "**Restricted Area**"). Nothing herein shall prohibit Seller or any of its Affiliates from (A) being a passive owner of not more than two percent of the outstanding equity interest in any entity that is publicly traded or (B) selling products to, servicing, soliciting or receiving products or services from or otherwise engaging in any commercial activities with (in each case, in the ordinary course of business) a Person engaged in the Restricted Business or any customer, supplier, licensor or licensee of Buyer so long as Seller or its Affiliates does not engage in or participate in the Restricted Business. Seller expressly acknowledges on behalf of itself and its Affiliates that the limitation with respect to the Restricted Area is reasonable and necessary to protect the legitimate business interests of Buyer and its Affiliates, especially given the special information and knowledge held by Seller and its Affiliates with respect to the Restricted Business and Acquired Assets. Further, Seller acknowledges that Buyer would not proceed with the transactions contemplated by this Agreement without receiving the full scope of the protections provided for hereunder; and that any lesser geographic restriction would not adequately protect Buyer, its Affiliates and the Restricted Business and the Acquired Assets.

(b) In the event that, prior to the expiration of the Restricted Period, Seller or one of its applicable Affiliates enters a process of voluntary or involuntary liquidation, Seller agrees that it, or such applicable Affiliate, shall assign to Buyer such party's rights to enforce its employee non-competition agreements; provided, that the restriction on competition to be assigned to Buyer is limited solely with respect to the Restricted Business and Acquired Assets.

(c) Seller shall not, and shall not permit any of its Affiliates to, at any time during the Restricted Period, and except with the written consent of Buyer, directly or indirectly, either for such Seller, its Affiliates or for or in collaboration with any other Person, recruit or otherwise solicit or induce any customer, subscriber, service provider, supplier or other business partner of Buyer to (i) terminate its arrangement or cease to do business with Buyer or its Affiliates to the extent it relates to the Restricted Business or the Acquired Assets, or (ii) to otherwise adversely modify its relationship with Buyer or its Affiliates to the extent it relates to the Restricted Business or the Acquired Assets. Seller shall not, and shall not permit any of its Affiliates to, at any time during the Restricted Period, directly or indirectly, either for Seller, its Affiliates or for or in collaboration with any other Person, solicit any employee, consultant or independent contractor of Buyer or its Affiliates engaged in the Restricted Business to terminate his or her employment or service with Buyer or its Affiliates; provided, that Seller and its Affiliates shall not be prohibited by this Section 6.7(c) from engaging in general advertising or solicitation not specifically directed at Buyer's or its Affiliates' customers, subscribers, service providers, suppliers or other business partners or employees, consultants or independent contractors.

6.8 **Audit Cooperation**. Following the Closing, upon written request by Buyer, Seller shall, and shall cause its Affiliates, at Buyer's expense, to reasonably cooperate with Buyer or its Affiliates, as applicable, in obtaining an audit of the applicable financial statements of Seller solely with respect to the Acquired Assets, to the extent Buyer determines, upon the advice of legal counsel, that such audit is required in connection with an initial public offering.

6.9 **Bulk Sales Laws**. The Parties hereby waive compliance with the provisions of any bulk sale, bulk transfer, or similar Laws of any jurisdiction that may otherwise be applicable with respect to the sale of any or all of the Acquired Assets to Buyer, it being understood and agreed that any Liabilities arising out of the failure to

comply with the requirements and provisions of any such Laws of any jurisdiction shall be treated as Excluded Liabilities.

6.10 **Clinical Data**. In the event that, prior to the Closing Date, Seller has obtained the [***] data (including the CSRs from the [***] Studies (the "[***] **Data**")) related to the Compound, including all clinical trial data, from [***] and [***] (collectively, including the [***] Data, the "[***] **Data**"), and such [***] Data is deemed an Acquired Asset transferred to Buyer at Closing, then Buyer acknowledges and agrees that the cost of obtaining such [***] Data is included as an expense set forth on Schedule 4.6.

## 7. INDEMNIFICATION AND LIMITATION OF LIABILITY

7.1 **Indemnification**.

(a) **Indemnification by Buyer**. From and after the Closing, subject to the provisions of this Article 7, Buyer shall defend, indemnify, and hold Seller and its Affiliates and their respective officers, directors, employees, and agents (collectively, the "**Seller Indemnitees**") harmless from and against any and all loss, claim, demand, obligation, judgement, damage, fine, deficiency, penalty, Liability, Tax, or other cost, expense or adverse effect whatsoever, whether or not arising out of or involving the claims of a Third Party or incurred with investigating, defending or settling any of the foregoing (including reasonable attorneys' or other reasonable professional fees and expenses and court costs) (collectively, "**Loss**") suffered by any Seller Indemnitee resulting from or arising out of: (i) any inaccuracy in or breach of any representation or warranty by Buyer under this Agreement, any Transaction Document or any certificate or instrument delivered by or on behalf of Buyer pursuant to this Agreement, (ii) any breach by Buyer of, or any failure by Buyer to perform, any covenant or agreement of, or required to be performed by, Buyer under this Agreement, (iii) any Claim from a Third Party based upon, resulting from or arising out of the development, manufacture, commercialization, or other exploitation of the Acquired Assets after the Closing with respect to circumstances, actions, events or conditions occurring or existing following the Closing (a "**Third Party Post-Closing Claim**"); provided, that such circumstance, action, event or condition was not occurring or existing on or before the Closing Date, (iv) any Assumed Liabilities, and/or (v) any Fraud of Buyer or its Affiliates.

(b) **Indemnification by Seller**. Seller shall defend, indemnify, and hold Buyer and its Affiliates and their respective officers, directors, employees, and agents (collectively, the "**Buyer Indemnitees**") harmless from and against any and all Losses suffered by any Buyer Indemnitee to the extent resulting from or arising out of: (i) any inaccuracy in or breach of any representation or warranty by Seller under this Agreement, any Transaction Document or any certificate or instrument delivered by or on behalf of Seller pursuant to this Agreement, (ii) any breach by Seller of, or any failure by Seller to perform, any covenant or agreement of, or required to be performed by, Seller under this Agreement, (iii) any Claim from a Third Party based upon, resulting from or arising out of the business, operations, assets of obligations of Seller or its Affiliates or the development or manufacture of the Acquired Assets, in each case, occurring or existing on or before the Closing Date, (iv) any Excluded Asset, (v) any Excluded Liabilities, and/or (vi) any Fraud of Seller or its Affiliates.

(c) **Indemnification Procedures**. The Party seeking indemnification (individually, the "**Indemnified Party**") shall promptly notify the other Party (each, an "**Indemnifying Party**") in writing of any claim ("**Claims**") for indemnification (a "**Claim Notice**"); provided, however, that any failure or delay by the Indemnified Party in delivering a Claim Notice to the Indemnifying Party shall not affect the Indemnified Party's right to indemnification under this Article 7, except to the extent the Indemnifying Party has been actually and materially prejudiced by such failure or delay. Such

Claim Notice shall indicate the nature of the Claim, the basis therefor and the amount of Losses such Indemnified Party has incurred or anticipates it will incur, to the extent reasonably known by such Indemnified Party. If the Indemnifying Party disputes the amount of, or its liability with respect to, a Claim Notice, the Indemnifying Party may notify the Indemnified Party in writing within 30 days of receipt of a Claim Notice (an "**Objection Notice**," and such date, the "**Objection Date**"), and the Parties shall attempt in good faith for a period of up to 30 days to agree upon the rights of the respective parties with respect to the claim. If the Parties do not reach an agreement by the conclusion of such 30-day period, then either Seller or Buyer may bring suit to resolve the Parties' respective rights with respect to such Claim, and the applicable Governmental Authority shall determine the final amount of any Losses (if any) with respect to such Claim. If the Indemnifying Party does not timely deliver an Objection Notice, the Claims (and the amount of Losses related thereto) shall be deemed to be accepted by the Indemnifying Party. If such Claim is a result of a Third Party making a Claim against an Indemnified Party, the Indemnifying Party shall have the right (but not the obligation to) at its option and expense, assume the complete defense of such Claim, provided that (i) the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense, (ii) the Indemnifying Party will conduct the defense of any such Claim with due regard for the business interests and potential related liabilities of the Indemnified Party, and (iii) the Indemnifying Party will not agree to any settlement that would admit liability on the part of the Indemnified Party or involve relief other than payment of money, without the approval of the Indemnified Party, not to be unreasonably withheld, conditioned or delayed; provided, that if it is reasonably likely that the Parties may have conflicting interests or if it is otherwise not advisable under applicable legal and ethical requirements for the Indemnifying Party's defense counsel to represent both Parties (as reasonably determined by the Indemnified Party), separate independent counsel shall be retained for each Party at its own expense. The Indemnifying Party will not, in defense of any such Claim, except with the consent of the Indemnified Party, consent to the entry of any judgment or enter into any settlement which does not include, as an unconditional term thereof, the giving by the claimant or plaintiff to the Indemnified Party of a release from all liability in respect thereof. After notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of such Claim, the Indemnifying Party shall be liable to the Indemnified Party for such legal or other expenses subsequently incurred by the Indemnified Party in connection with the defense thereof at the request of the Indemnifying Party. As to those Claims with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such defense at the Indemnifying Party's own cost and expense, and will not settle or otherwise dispose of any of the same without the consent of the Indemnifying Party; provided, that, for the avoidance of doubt, the Indemnifying Party shall indemnify the Indemnified Party for any Loss incurred in connection with a Claim in which the Indemnified Party controls the defense. The time limits set forth in Section 7.2 or Section 7.3 for making claims for indemnification are in lieu of, and the Parties expressly waive, any other applicable statute of limitations during which such claims may be brought or asserted. Any notice for indemnification made pursuant to this Section 7.1(c) prior to the expiration of the time limit set forth in Section 7.2 or Section 7.3, as applicable, for the matter against which indemnity is sought shall for purposes of the time limits set forth in Section 7.2 or Section 7.3, as applicable, constitute a claim or demand brought within such time limit, and the obligations of the Indemnifying Party therefor under this Article 7 shall continue as to such matter, notwithstanding the expiration, if any, of such time limit.

7.2 **Survival of Representations and Warranties**. Except in the case of matters relating to Fraud, all representations and warranties contained in this Agreement, any Transaction Document or in any certificate or instrument delivered pursuant to this Agreement will survive the Closing for a period of 12 months from the Closing

Date; provided, however, notwithstanding the foregoing, the respective representations and warranties of the Parties set forth in Section 5.1(a) (*Organization*), Section 5.1(b)(i) (*Due Authorization; No Conflict*), Section 5.1(d) (*Brokers*), Section 5.2(a) (*Organization*), Section 5.2(b)(i) (*Due Authorization; No Conflict*), Section 5.2(c)(i), (iii), (iv) (*Acquired Assets*) and Section 5.2(l) (*Brokers*) shall survive the Closing for a period ending upon the date that is 60 days after the expiration of the applicable statute of limitations for each of the matters set forth therein; provided, further, that, notwithstanding anything to the contrary herein, the representations and warranties of Seller set forth in Section 5.2(f) (*Tax Matters*) shall survive the Closing for a period of 18 months from the Closing Date. Claims arising from, relating to or for Fraud shall survive the Closing indefinitely. The Parties further acknowledge that each of the survival periods in this Section 7.2 is the result of arm's-length negotiation among the Parties and that the Parties intend for such survival periods to be enforced as agreed by the Parties.

7.3 **Limitations**.

(a) No Party will be liable to any other Party or any Indemnified Party for indemnification under Section 7.1(a)(i) or Section 7.1(b)(i) unless and until the aggregate amount of all Losses suffered by such Party exceeds $25,000 (the "**Deductible**"), in which event, the Indemnifying Party shall be liable for Losses in excess of the Deductible.

(b) The maximum aggregate amount of indemnifiable Losses that may be recovered from Seller by Buyer Indemnitees pursuant to Section 7.1(b)(i), shall be an amount equal to the sum of (i) the Upfront Expense Reimbursement Amount and (ii) that number of shares of Common Stock of Buyer deemed as Clawback Shares (such sum, the "**Seller Cap**").

(c) The maximum aggregate amount of indemnifiable Losses that may be recovered from Buyer by the Seller Indemnitees pursuant to Section 7.1(a)(i) shall be an amount equal to the Upfront Expense Reimbursement Amount (the "**Buyer Cap**").

(d) No Claim against Buyer and its Affiliates or Seller and its Affiliates, as applicable, pursuant to Section 7.1(a)(ii) or Section 7.1(b)(ii), as applicable, with respect to a breach of or failure to perform any covenant or agreement to be performed after the Closing shall be brought or asserted after the date of expiration of the applicable statute(s) of limitations applicable thereto.

(e) Notwithstanding anything in this Agreement to the contrary, for purposes of the indemnification obligations of Seller under Section 7.1(b), the representations and warranties set forth in Article 5 of this Agreement that are qualified as to materiality, in all material respects, material adverse effect or any similar qualification shall be deemed to have been made without any such qualification for purposes of determining whether there has been a breach of any representation and warranty and for purposes of calculating the amount of Losses incurred by a Buyer Indemnitee seeking indemnification hereunder arising out of or resulting from such breach of a representation, warranty, covenant or agreement contained herein.

(f) Notwithstanding anything in this Article 7 to the contrary, in the event of any breach of a representation or warranty in this Agreement or any other Transaction Document that results from Fraud by or on behalf of any Person then, (i) such representation or warranty will survive the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby indefinitely, notwithstanding that such survival might otherwise be limited by the applicable survival date, (ii) any limitations on Losses set forth in this Article 7 shall not apply to any Loss that Buyer Indemnitees or the Seller Indemnitees, respectively, may suffer, incur, sustain or become subject to, as a result of, arising out of, relating to or in connection with any such breach, and (iii) none of such Losses shall be limited or restricted by the Seller Cap or Buyer Cap, as applicable.

(g) Each Indemnified Party shall take and shall cause their respective Affiliates to take all commercially reasonable steps to mitigate Losses to the extent required by Law upon and after becoming aware of any event which would reasonably be expected to give rise to any Losses, including without limitation pursuing recoveries against Third Parties, except that such Indemnified Party shall not be required to commence litigation against any insurer or Third Party. The reasonable costs and expenses of mitigation hereunder shall constitute indemnifiable Losses under this Agreement.

(h) In no event shall any Indemnifying Party be liable to any Indemnified Party for any consequential, speculative, loss of profits, special, indirect or punitive damages (except for amounts actually paid or payable to a Third Party by an Indemnified Party).

(i) Notwithstanding anything contained herein to the contrary, the amount of any Losses incurred or suffered by an Indemnified Party shall be calculated after giving effect to any insurance proceeds actually received by such Indemnified Party with respect to such Losses, less any related costs and expenses, including the aggregate cost of pursuing any related insurance claims and related increases in insurance premiums or other chargebacks. If any insurance proceeds are received by any Indemnified Parties with respect to any Losses after Seller or Buyer (as applicable) has made a payment to such Indemnified Parties with respect thereto, the Indemnified Parties shall promptly pay to Seller or Buyer (as applicable) the sum of the amount of such proceeds up to the amount of the payment to the Indemnified Party's less any of the Indemnified Party's related costs and expenses of recovering such insurance proceeds, including the aggregate cost of pursuing any related insurance claims and related increases in insurance premiums or other chargebacks.

7.4 **Timing and Order of Payment**. Subject to Section 7.5, after (x) any final decision, judgment or award shall have been rendered by a Governmental Authority of competent jurisdiction, (y) the Objection Date shall have lapsed and no Objection Notice has been delivered, or (z) the Indemnifying Party and Indemnified Party shall have arrived at a mutually binding agreement with respect to a Claim, the indemnification payments required to be made pursuant to this Article 7 shall be paid within 10 Business Days of the final determination of the amount of an indemnification Claim in accordance with this Article 7. In the event any Buyer Indemnitee shall suffer any Losses for which such Buyer Indemnitee is entitled to indemnification under this Article 7, such Buyer Indemnitee shall be entitled, subject to the limitations set forth in Section 7.3(b), to recover such Losses (a) first, at Buyer's option, from Seller, in cash in immediately available funds up to the Upfront Expense Reimbursement Amount and (b) thereafter, to the extent such Losses exceed the Upfront Expense Reimbursement Amount, in accordance with Section 7.5.

7.5 **Clawback Shares**.

(a) In the event any Buyer Indemnitee shall suffer any Losses that are finally determined pursuant to Section 7.1(c) and 7.4 for which such Buyer Indemnitee is entitled to indemnification under this Article 7, and such Losses exceed the Upfront Expense Reimbursement Amount or Buyer determines to not recover from the Upfront Expense Reimbursement Amount, then Seller shall surrender and forfeit the number of Clawback Shares equal in value (determined in accordance with Section 7.5(b)) to the Losses suffered by such Buyer Indemnitee in respect of such Claim (less any applicable recovery by Buyer from the Upfront Expense Reimbursement Amount in accordance with Section 7.4) (each such instance, a "**Share Clawback**"). In the event of a Share Clawback, the number of shares constituting Clawback Shares for purposes of such Share Clawback shall be surrendered and forfeited by Seller to Buyer or its designee, and Buyer shall have the right to affirmatively cancel such Clawback Shares with no further action required by Seller, for no consideration (it being acknowledged and agreed that such Clawback Shares are being delivered in satisfaction of Seller's obligation to indemnify the Buyer Indemnitees). For the avoidance of doubt,

following a Share Clawback, the number of shares constituting Clawback Shares shall be reduced by the number of shares surrendered and forfeited pursuant to such Share Clawback.

(b) For purposes of determining the number of Clawback Shares to be surrendered and forfeited pursuant to a Share Clawback, each Clawback Share shall be ascribed a value per share equal to the then-current independent valuation of the Common Stock of Buyer on the date on which the applicable indemnification Claim (and Losses related thereto) is finally determined pursuant to Section 7.1(c) and 7.4.

(c) On the Clawback Expiration Date, subject to Section 7.5(f) in respect of any Pending Claim, any remaining shares of Common Stock of Buyer constituting Clawback Shares shall no longer constitute Clawback Shares and shall no longer be subject to this Section 7.5.

(d) Notwithstanding anything to the contrary herein, if no Share Clawback occurs prior to the Clawback Expiration Date, subject to Section 7.5(f) in respect of any Pending Claim, the Clawback Shares shall remain the sole property of the Seller.

(e) Until the Clawback Expiration Date, Seller agrees that it will hold and will not, directly or indirectly, without the Buyer's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), sell, transfer or otherwise dispose of any Clawback Shares, or otherwise make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale of the Clawback Shares (any such transaction, a "**Transfer**"); provided, that the foregoing shall not prohibit (i) Seller from Transferring any Clawback Shares to Buyer or its Affiliates; (ii) the disposition or other Transfer of Clawback Shares pursuant to (A) any merger, consolidation or similar transaction to which Buyer is a constituent corporation or (B) a bona fide tender offer or exchange offer made to all of the holders of Common Stock of Buyer by a Third Party. Notwithstanding the foregoing, subject to Section 7.5(f) in respect of any Pending Claim, the transfer restrictions and the Share Clawback right shall automatically terminate and be of no further force or effect on the Clawback Expiration Date.

(f) Notwithstanding anything to the contrary herein, if any Claim pursuant to this Article 7 shall have been properly asserted by any Buyer Indemnitee in accordance with Section 7.1 and prior to the Clawback Expiration Date, and such Claim(s) remains pending as of the Clawback Expiration Date (any such Claim(s), a "**Pending Claim**"), then Seller agrees that a number of Clawback Shares equal in value (in accordance with Section 7.5(b)) to Buyer's Board of Directors good faith determination of the aggregate amount of such Pending Claim shall remain subject to Share Clawback until the resolution or (if applicable) satisfaction of such Pending Claim in accordance with Section 7.1(c) and 7.4.

(g) Each Party acknowledges and agrees that the agreements contained in this Article 7 are an integral part of the transactions contemplated by this Agreement and the other Transaction Documents, and that, without these agreements, the Parties would not enter into this Agreement and the other Transaction Documents. In particular, each Party acknowledges and agrees that the Share Clawback is not a penalty, but rather a reasonable mechanism to compensate the Buyer Indemnitees in the event such Buyer Indemnitees have suffered Losses in excess of the Upfront Expense Reimbursement Amount prior to the Clawback Expiration Date.

(h) In the event Buyer undergoes any share split, combination, reclassification, bonus issue of shares or similar capitalization change with respect to shares of Common Stock of Buyer prior to the Clawback Expiration Date, appropriate and proportionate adjustments shall be made to the shares of Common Stock of Buyer comprising the Clawback Shares.

7.6 **Sole Remedy**. Except in the case of matters relating to Fraud, from and after the Closing, the sole and exclusive remedy of any Indemnified Party for any breach of any representation, warranty, covenant or other claim arising out of or relating to this Agreement and/or the transactions contemplated hereby is set forth in this Article 7; provided, however, that notwithstanding the foregoing: (a) the Parties shall be entitled to enforce the right to specific performance as set forth in Section 9.9, and (b) the parties to the Transaction Documents shall be entitled to enforce the terms of each of the Transaction Documents (as applicable), and for the avoidance of doubt, this Section 7.6 shall not apply to the Transaction Documents other than this Agreement.

## 8. OTHER AGREEMENTS

8.1 **Purchase Option**.

(a) If Buyer or its Affiliates have not yet consummated a Qualified Financing on or prior to the Resolution Period End Date (the "**Purchase Condition**"), Seller shall have the right (but not the obligation) (the "**Purchase Option**"), subject to the provisions of this Section 8.1, to purchase from Buyer and/or its Affiliates, as applicable, all, but not less than all, of Buyer's rights, title and interest in and to the Acquired Assets and all improvements and developments thereon (collectively, the "**Buyer Program Assets**") for an aggregate purchase price equal to the Purchase Option Price. If the Purchase Condition has not been met by the Resolution Period End Date, Seller may exercise the Purchase Option by delivery of written notice to Buyer at any time on or after the Resolution Period End Date and before the Series A Financing (as defined in the Stock Issuance Agreement) (a "**Option Exercise Notice**").

(b) Upon receipt of an Option Exercise Notice, the closing of the Purchase Option (the "**Purchase Option Closing**") shall occur by remote means on a date to be mutually agreed by Buyer (or its Affiliate) and Seller, which date shall be no later than 60 days following delivery of the Option Exercise Notice. At the Purchase Option Closing, Buyer (or its Affiliate) and Seller shall deliver definitive documentation, substantially similar to this Agreement, to consummate the transactions contemplated by the Purchase Option; provided, that the only representations that Buyer or its Affiliate, as applicable, shall make to Seller with respect to the Buyer Program Assets thereunder shall be representations generally consistent with Seller's representations contained in Section 5.2(a) (Organization), Section 5.2(b) (Due Authorization; No Conflict) and Section 5.2(c) (Acquired Assets), Section 5.2(e) (Intellectual Property) and Section 5.2(h) (Regulatory Matters).

(c) At the Purchase Option Closing, Seller shall pay cash in an amount equal to the Purchase Option Price and Buyer or its Affiliate, as applicable, shall deliver to Seller the Acquired Assets, free and clear of all Liens (other than Permitted Encumbrances).

8.2 **Post-Closing Covenants**. From the Closing until the termination of this Article 8, except (x) as expressly provided in this Agreement or any other Transaction Document, (y) with the prior written consent of Seller (not to be unreasonably withheld, conditioned or delayed) or (z) as required by Law, (i) Buyer shall use commercially reasonable efforts to maintain the Acquired Assets and Assumed Contracts in such a manner as to permit Buyer or any successor owner to continue to conduct the development, testing, safety and efficacy, of the Compound during such period in all respects in substantially the same manner as Seller or its Affiliates have conducted the same through the date hereof, (ii) Buyer shall not assign, sell, offer to sell, pledge, mortgage, hypothecate, incur any Liens (other than Permitted Encumbrances) upon, dispose or otherwise transfer, any of the Acquired Assets or Assumed Contracts to a Third Party, (iii) Buyer shall not undergo any Liquidation Event, and (iv) Buyer shall provide Seller a written notice that it has received minutes of the FDA Meeting promptly, but no later than five Business Days, following the date of Buyer's receipt of such minutes. Buyer shall promptly provide Seller copies of any amendments, modifications, terminations or waiver agreements related to the Fuji License Agreement.

8.3 **Briefing Book**. As soon as reasonably practicable following the Closing, Buyer shall provide Seller with drafts and revisions of the meeting request and the briefing book (including any attachments) intends to submit to the FDA in connection with the FDA Meeting (collectively, the "**Briefing Book**"); provided, however, that each Party agrees and acknowledges that Buyer shall not be required to provide an updated draft of the Briefing Book to Seller more than once per calendar week (or more frequently to the extent any material updates or revisions were made to such Briefing Book since the last version provided), except that Buyer will provide Seller with further updated drafts of the Briefing Book as frequently as reasonably practicable in the calendar week prior to submission of the Briefing Book to the FDA.

8.4 **Termination of Article 8**. This Article 8 shall automatically terminate, and be of no further force or effect, upon a Sunset Event (as defined in the Stock Issuance Agreement).

**9. MISCELLANEOUS**

9.1 **Entire Agreement; Amendments**. This Agreement, together with the remainder of the Transaction Documents, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and thereof, and supersedes all prior agreements and understandings between the Parties with respect to the subject matter hereof and thereof, including the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

9.2 **Notices**. Any notice, demand or communication required, permitted or desired to be given hereunder shall be deemed effectively given when personally delivered with signed receipt, when delivered by electronic mail with electronic confirmation of delivery (unless not delivered on a Business Day or delivered after 5:00 p.m. Pacific Time on a Business Day, in which case such delivery shall be deemed effective on the next succeeding Business Day), when delivered by overnight courier with signed receipt, and delivery shall be deemed effective on the next succeeding Business Day, addressed to the addresses below or to such other address as any Party may designate, with copies thereof to the respective counsel thereof as notified by such Party.

If to Buyer:

Crystalys Therapeutics, Inc.
100 Pine St. Ste #1250
San Francisco, CA 94111
Email: [***]
Attention: [***]

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92130
Email: cheston.larson@lw.com; kevin.reyes@lw.com; christian.hollweg@lw.com
Attention: Cheston J. Larson; Kevin C. Reyes; Christian Hollweg

If to Seller:

Urica Therapeutics, Inc.

1111 Kane Concourse, Suite 301
Bay Harbor Islands, FL 33154
Email: legal@fortressbiotech.com
Attention: Legal Department

with a copy (which shall not constitute notice) to:

DLA Piper LLP (US)
Harbor East
650 S. Exeter Street, Suite 1100
Baltimore, Maryland 21202-4576
Email: howard.schwartz@us.dlapiper.com
Attention: Howard S. Schwartz, esq.

9.3 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement and the other Transaction Documents.

9.4 **Public Announcements**. No Party shall issue any public announcement, press release, or other public disclosure regarding the Transaction Documents or their subject matter without the other Party's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), except for any such disclosure that is required by applicable Law or the disclosure requirements of any stock exchange on which securities issued by a Party are traded. Buyer and Seller may issue a press release announcing the consummation of the transactions contemplated by this Agreement in a form reasonably agreed to by both Buyer and Seller.

9.5 **Severability**. If any of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

9.6 **No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

9.7 **Governing Law**. Resolution of all disputes, controversies or claims arising out of, relating to or in connection with this Agreement or the performance, enforcement, breach or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of Delaware, without regard to conflicts of law rules.

9.8 **Waiver of Jury Trial**. EACH OF THE PARTIES HERETO WAIVES TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. EACH OF THE PARTIES HERETO HEREBY: (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, AND (B) ACKNOWLEDGES THAT IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, AS

APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 9.8.

9.9 **Enforcement**. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. Accordingly, each Party shall be entitled to specific performance of the terms hereof, including an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware declines to accept jurisdiction over a particular matter, any federal or state courts located in the State of Delaware), this being in addition to any other remedy to which such Party is entitled at law or in equity and in addition to the right to seek indemnification pursuant to Article 7. Each Party hereby further waives (a) any defense in any Proceeding for specific performance that a remedy at law would be adequate and (b) any requirement under any Law to post security or bond as a prerequisite to obtaining equitable relief.

9.10 **Cumulative Remedies**. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth herein.

9.11 **No Benefit to Third Parties; No Assignment**. Except for the Persons entitled to indemnification under Article 7, the provisions of this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any Third Party, and no Third Party may seek to enforce, or benefit from, these provisions. The Parties specifically disavow any desire or intention to create any third-party beneficiary hereunder, and specifically declare that no Person, except for the Parties and their successors, shall have any right hereunder nor any right of enforcement hereof. No Party may transfer, assign or otherwise convey any of its rights or delegate any of its obligations under this Agreement, by operation of Law or otherwise, without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed).

9.12 **Construction of this Agreement**. When used in this Agreement, the term “including”, “include” or “includes” means including, without limiting the generality of any description preceding the term. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). “$” refers to United States dollars. References to either Party include the successors and permitted assigns of that Party. The headings and table of contents of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. Any reference to a Law includes (a) any regulation or rule promulgated under such Law and (b) any binding interpretation of such Law. Any reference to a Law with respect to a given point in time includes any amendment, modification, or replacement of such Law in effect at such time. The Parties have each consulted counsel of their choice regarding this Agreement and have jointly prepared this Agreement, and, accordingly, no provisions of this Agreement shall be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. If the terms of this Agreement conflict with the terms of any Exhibit, Schedule, or other Transaction Document, then the terms of this Agreement shall govern solely as to the extent of such conflict unless otherwise expressly stated otherwise. “Exhibit” refers to an exhibit to this Agreement (which, in each case, is incorporated herein by reference), unless otherwise stated in this Agreement. “Schedule” refers to a schedule to this Agreement and incorporates any attachments thereto (which, in each case, are incorporated herein by reference), unless otherwise stated in this Agreement. This Agreement has been prepared in the English language and English shall control its interpretation. Reference to any Contract (including this Agreement), document, or instrument shall mean such Contract, document, or instrument as amended or modified and in effect from time to time in accordance with the terms thereof and, if applicable, the terms of this Agreement. Reference to any statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. Reference to any period of days shall be deemed to be to the relevant number of calendar days unless

otherwise specified. When calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date for calculating such period shall be excluded. If the last day such period is a non-Business Day, the period in question shall end on the next succeeding Business Day. References to articles, sections, clauses, exhibits or schedules shall refer to those portions of this Agreement. The use of the terms "hereunder," "hereof," "hereto," "herein," and words of similar import shall refer to this Agreement as a whole (including the Exhibits and Schedules hereto) and not to any particular article, section, paragraph, or clause of, or exhibit or schedule to, this Agreement unless otherwise indicated. All terms defined in this Agreement have the defined meanings when used in any certificate or other document made or delivered pursuant to this Agreement, unless otherwise defined in such certificate or other document.

9.13 **Relationship of the Parties**. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture or legal entity of any type between Seller and Buyer, or to constitute one as the agent of the other. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind or commit the other.

9.14 **Expenses**. Except as otherwise specified in this Agreement, each Party hereto shall pay its own legal, accounting, due diligence, out-of-pocket and other expenses incident to this Agreement and to any action taken by such Party in preparation for carrying this Agreement and the other Transaction Documents into effect.

9.15 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute together the same document. Any signature page delivered via any means of electronic communication shall be binding to the same extent as an original signature page.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the Parties have duly executed this Agreement by their proper officers as of the Closing Date.

**URICA THERAPEURTICS, INC.**

By: /s/ Jay Kranzler
Name: Jay Kranzler
Title: Chief Executive Officer

**CRYSTALYS THERAPEUTICS, INC.**

By: /s/ Brian Taylor Slingsby
Name: Brian Taylor Slingsby, MD, PhD, MPH
Title: Chief Executive Officer

**Exhibit A**

**Assignment and Assumption Agreement**

**Exhibit B**

**Bill of Sale**

B-1

**Exhibit C**

**Patent Assignment**

C-1

**Exhibit D**

**Purchased Deliverables**

D-1

**Exhibit E**

**Royalty Agreement**

E-1

**Exhibit F**

**Security Agreement**

**Exhibit G**

**Stock Issuance Agreement**

G-1

**Exhibit H**

**Voting Agreement**

H-1

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

**Exhibit 10.5**

# ROYALTY AGREEMENT

This Royalty Agreement (this "**Agreement**") is made and entered into as of July 15, 2024 (the "**Effective Date**") by and between **CRYSTALYS THERAPEUTICS, INC.**, a Delaware corporation having a place of business at 100 Pine St. Ste #1250, San Francisco, CA 94111 ("**Crystalys**"), and **URICA THERAPEUTICS, INC.**, a Delaware corporation having a place of business at 1111 Kane Concourse Suite 301, Bay Harbor Islands, FL 33154 ("**Urica**"). Crystalys and Urica are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

## RECITALS

**WHEREAS**, as a condition of, and in order to induce Urica to enter into, that certain Asset Purchase Agreement, of even date herewith (as amended, restated or modified from time to time, "**APA**"), pursuant to which, upon Closing (as defined in the APA), Urica shall sell, transfer, convey, assign and deliver to Crystalys, and Crystalys shall purchase and acquire from Urica, the Acquired Assets (as defined in the APA), the Parties have agreed to enter into this Agreement, pursuant to which Crystalys shall convey, and Urica shall receive, as partial consideration for the Acquired Assets, the Royalty Interest Right (as defined below) on the terms and conditions set forth in this Agreement;

**WHEREAS**, as a condition of, and in order to induce Urica to enter into the APA and this Agreement, the Parties have agreed to enter into that certain Security Agreement, of even date herewith (as amended, restated or modified from time to time, the "**Security Agreement**"), pursuant to which Crystalys will provide Urica a continuing, perfected lien on, and security interest in, the Collateral (as defined therein); and

**WHEREAS**, it is the intent of the Parties that the transactions under and as contemplated herein shall constitute a true sale of, *inter alia*, the Royalty Interest from Crystalys to Urica (as partial consideration to Urica for the sale of the Acquired Assets by Urica to Crystalys).

**NOW, THEREFORE**, in consideration of the foregoing premises and the respective representations, warranties, covenants, agreements and conditions contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

## 1. DEFINITIONS

Capitalized terms used in this Agreement (other than the headings of the Sections or Articles) have the following meanings set forth in this Article 1 (Definitions), or, if not listed in this Article 1 (Definitions), have the meanings ascribed thereto in the APA.

1.1 "**Acceptable Intercreditor Agreement**" means any intercreditor agreement, substantially in the form set forth in Exhibit A.

1.2 "**Acquired Assets**" has the meaning set forth in the APA.

1.3 "**Affiliate**" means with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. As used in this Section 1.3, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of at least 50% of the voting stock of such entity, or by contract or otherwise. The Parties acknowledge that in the case of entities organized under the laws of certain countries where the maximum percentage ownership permitted by law for a foreign investor is less than 50%, such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding anything to the contrary herein, whether prior to or following the effective date of this Agreement, neither Crystalys nor its Affiliates shall be deemed an Affiliate of Urica under this Agreement, and Urica shall not be deemed an Affiliate of Crystalys or its Affiliates under this Agreement.

1.4 "**Bankruptcy Laws**" means, collectively, bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, fraudulent transfer or other similar laws affecting the enforcement of creditors' rights generally.

1.5 "**Business Day**" means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in California are permitted or required by applicable law or regulation to remain closed.

1.6 "**Change of Control**" means, with respect to a Person: (a) a transaction or series of related transactions that results in the sale, lease, transfer, license or sub-license or other disposition of all or substantially all of such Person's assets or the assets of such Person, taken as a whole (other than any such sale or other disposition to a subsidiary or Affiliate of such Person), on a consolidated basis to a Third Party; or (b) a merger or consolidation in which the equityholders of such Person immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of the surviving entity's (or surviving entity's parent's) outstanding equity securities; or (c) a transaction or series of related transactions (which may include: (x) a tender offer for such Person's equity; or (y) the issuance, sale or exchange of equity securities of such Person other than in one or more bona fide capital raising transactions) if the stockholders of such Person immediately prior to the initial such transaction do not, immediately after consummation of such transaction or any of such related transactions, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of such Person's or its successor's outstanding equity securities.

1.7 "**Collateral**" has the meaning set forth in the Security Agreement.

1.8 "**Combination Product**" has the meaning set forth in the Fuji License Agreement (as in effect as of the Effective Date). For the avoidance of doubt, all Combination Products are also Purchased Products.

1.9 "**Commercialization**" means any and all activities undertaken at any time for a Licensed Product (as defined in the Fuji License Agreement in effect as of the Effective Date) and that relate to the manufacturing, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Licensed Product (as defined in the Fuji License Agreement in effect as of the Effective Date), and interacting with Regulatory Authorities regarding the foregoing.

1.10 "**Commercially Reasonable Efforts**" means, with respect to an obligation regarding development of any Licensed Product (as defined in the Fuji License Agreement in effect as of the Effective Date), such efforts that are consistent with the efforts and resources normally used by a comparable biotechnology or pharmaceutical company in the performance of such an obligation for a similar pharmaceutical or biological product (including the research, Development (as defined in the Fuji License Agreement in effect as of the Effective Date), manufacture, and Commercialization of a pharmaceutical or biological product), as applicable, at a similar stage in its research, development, or commercial life as such Purchased Product, and that has commercial and market potential similar to such Purchased Product, taking into account issues of intellectual property coverage, safety and efficacy, stage of development, costs, product profile, competitiveness of the market place, proprietary position, regulatory exclusivity, anticipated or approved labeling, corporate resources, present and future market and commercial potential, the likelihood of receipt of regulatory approval, profitability (including pricing and reimbursement status achieved or likely to be achieved), the existence and developmental stages of alternative products and programs, and legal issues.

1.11 "**Compound**" means any compound with the name (3,5-Dichloro-4-hydroxyphenyl)(1,1-dioxo-1,2-dihydro-3H-1λ6-1,3-benzothiazol-3-yl) methanone (IUPAC), including any salt, hydrate, racemates, isomers, polymorph, metabolites, or prodrugs thereof.

1.12 "**Confidential Information**" has the meaning set forth in Section 6.1.

1.13 "**Confidentiality Agreement**" has the meaning set forth in Section 6.3.

1.14 "**DACA**" has the meaning set forth in Section 5.2(a).

1.15 "**Development**" or "**Develop**" means, with respect to Purchased Product, the performance of all non-clinical, preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, manufacturing, regulatory activities that are required to obtain and maintain Regulatory Approval of such Purchased Product.

1.16 "**Disclosing Party**" has the meaning set forth in Section 6.1.

1.17 "**First Commercial Sale Date**" the date on which a Selling Party first ships a Purchased Product for commercial sale anywhere in the Territory pursuant to Regulatory Approval; provided, however, that if the sale has occurred in a country for which pricing or reimbursement approval is necessary for widespread sale, then the First Commercial Sale Date shall not occur until the pricing or reimbursement approval has been obtained. Sales for test marketing, sampling and promotional uses, clinical trial purposes, or compassionate or similar use shall not be considered for the First Commercial Sale Date.

1.18 "**Fiscal Quarter**" shall mean each of the three (3) consecutive calendar month periods ending on March 31, June 30, September 30, and December 31.

1.19 "**Fiscal Year**" each of the calendar year periods used by Crystalys for financial reporting, commencing on January 1 and ending on December 31.

1.20 "**Fuji**" means Fuji Yakuhin Co. Ltd.

1.21 "**Fuji License Agreement**" has the meaning set forth in the APA.

1.22 "**GAAP**" means generally accepted accounting principles in the United States in effect from time to time, consistently applied.

1.23 "**Governmental Authority**" means any multi-national, federal, state, local, municipal, or provincial government; any governmental or quasi-governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal); any tribunal, court of competent jurisdiction, administrative agency or commission or other governmental authority or body exercising or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power of any nature (in each case whether federal, state, local, foreign, international or multinational); any Regulatory Authority; or any arbitrator with authority to bind a party at Law.

1.24 "**Gross Invoice Amount**" has the meaning set forth in Section 1.30.

1.25 "**Indirect Taxes**" has the meaning set forth in Section 5.7(c).

1.26 "**Judgment**" means any judgment, order, writ, injunction, citation, award or decree of any nature.

1.27 "**Laws**" means all laws, statutes, rules, regulations, ordinances, codes, consent agreement, requirement, constitution, treaty, writ, injunction, judgment, ruling, decree or order, in each case, having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.28 "**Lien**" means any lien, mortgage, pledge, encumbrance, charge, security interest or charge of any kind or nature whatsoever.

1.29 "**Lien Release Trigger Amount**" means five hundred million dollars ($500,000,000).

1.30 "**Lien Release Trigger Date**" means the earliest of (i) the date in which the aggregate Royalty Payments paid by the Selling Parties exceeds the Lien Release Trigger Amount, (ii) the date in which this Agreement terminates pursuant to Section 7.1 or (iii) such other date as Urica agrees in writing.

1.31 "**Net Sales**" means the gross amount invoiced or otherwise charged by Crystalys, its Affiliates and/or their respective licensees and sublicensees ("**Selling Party**") to Third Parties for the sale of all Purchased Products in the Territory ("**Gross Invoice Amount**"), less:

(a) normal and customary trade, quantity, or cash discounts and credits allowed and taken;

(b) discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances given and taken that effectively reduce the net selling price, including, without limitation, Medicaid rebates, institutional rebates, or volume discounts;

(c) Purchased Product returns and allowances granted to the Third Party;

(d) administrative fees paid to group purchasing organizations (e.g., Medicare) and government-mandated rebates;

(e) shipping, handling, freight, postage, insurance, and transportation charges, but all only to the extent that these items are included as a separate line item in the gross amount invoiced;

(f) any taxes, tariffs or duties imposed on the production, sale, delivery or use of the Purchased Product, including, without limitation, sales, use, excise or value added taxes and customs and duties but excluding income tax, corporate income tax and gross receipts tax (in each case, to the extent such taxes are not paid by a Third Party);

(g) allowances for distribution expenses; and

(h) bad debt actually written off during the accounting period, as reported by the Selling Party in accordance with GAAP or IFRS, applied on a consistent basis.

Combination Products will be calculated by multiplying actual Net Sales of such Combination Products by the fraction A/(A+B), where "A" is the Net Sales price of the Purchased Product if sold separately, and "B" is the average Net Sales price, if sold separately, of the product containing the other active pharmaceutical ingredient in the Combination Product, in the most recent calendar quarter in which such products were sold. If the amount of the Compound or the other active pharmaceutical ingredient in the Combination Product is different from that in the products sold separately, A and B shall be adjusted in proportion to the amount of the active pharmaceutical ingredient contained.

In the event that, in any given country, no separate sale of either such abovedesignated Purchased Product (containing only such Purchased Product and no other active pharmaceutical ingredients) or any one or more of the active ingredients included in such Combination Product are made during the accounting period in which the sale was made or if the net selling price for an active pharmaceutical ingredient cannot be determined for an accounting period, Crystalys shall make a good faith determination of the Net Sales price of the Purchased Product.

Notwithstanding the above, any deductions shall be limited to those applied pursuant to Crystalys's standard operating procedures in accordance with general accepted accounting principles and to the extend such deductions differ from those set forth above, Crystalys shall provide written notice to Urica describing such differences.

The Purchased Product is considered "sold" when billed out or invoiced or, in the event the Purchased Product is not billed out or invoiced, when the consideration for sale of the Purchased Products is received. If a sale, transfer, or other disposition with respect to the Purchased Product involves consideration other than cash or is not at arm's length, then the Net Sales from the sale, transfer, or other disposition shall be calculated from the average selling price for the Purchased Product during the calendar quarter in the country where the sale, transfer, or disposition took place. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed to be zero with respect to : (i) Purchased Product used by a Selling Party for their internal use; (ii) the distribution of promotional samples of Purchased Product provided free of charge; (iii) Purchased Product provided for clinical trials or research, development, or evaluation purposes; or (iv) sales of Purchased Product among the Selling Parties for resale.

If either Party reasonably believes that the calculations set forth above regarding Combination Products do not fairly reflect the value of the Compound relative to the other active ingredients in the Combination Products, the Parties shall negotiate, in good faith and within six (6) months of being requested to do so, other means of calculating the Net Sales with respect to the Combination Products.

1.32 "**Obligors**" shall mean, collectively, Crystalys and the other grantors under the Security Agreement and their respective successors and permitted assigns.

1.33 "**Patents**" means any and all patents and patent applications, including any continuation, continuation-in-part, division, provisional or any substitute applications, any patent issued with respect to any of the foregoing patent applications, any certificate, reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent or other governmental actions which extend any of the subject matter of a patent, and any substitution patent, confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

1.34 "**Permitted Liens**" shall mean:

(a) Liens in favor or Urica (as secured party) created pursuant to the Security Agreement or any other document entered into in connection therewith or herewith;

(b) Liens securing equipment and software financing and leasing (including capital lease obligations and purchase money indebtedness; provided, that, the collateral therefor consists solely of the assets being financed, the products and proceeds thereof and books and records related thereto);

(c) Liens imposed by operation of Law related to carriers', warehousemen's, landlords', and mechanics' liens, liens relating to leasehold improvements and other similar Liens;

(d) pledges or deposits made (i) in connection with bids, leases, appeal bonds, workers' compensation, unemployment insurance or other similar social security legislation or (ii) securing liability for reimbursement or indemnification obligations of (including obligations in respect of letters of credit or bank guarantees) insurance carriers providing property, casualty or liability insurance;

(e) Liens for Taxes, assessments and other governmental charges not delinquent or that are being contested in good faith by appropriate proceedings diligently conducted, for which adequate reserves with respect thereto are being maintained in accordance with GAAP;

(f) any Liens existing as of the date hereof;

(g) servitudes, easements, rights of way, restrictions and other similar encumbrances on real property imposed by any Law and Liens consisting of zoning or building restrictions, easements, licenses, restrictions on the use of real property or minor imperfections in title thereto;

(h) (i) Liens that are contractual or common law rights of set-off relating to (A) the establishment of depository relations with banks or (B) pooled deposit or sweep accounts to permit satisfaction of overdraft or similar obligations, (ii) other Liens securing cash management obligations with depositary institutions and (iii) Liens encumbering customary initial deposits and margin deposits and similar Liens attaching to commodity trading accounts or other brokerage accounts;

(i) Liens securing (i) letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments issued or created, or related to obligations or liabilities incurred, (ii) workers compensation claims, health, disability or other employee benefits, or performance of commercial contracts, (iii) leases, subleases or liability insurance or self-insurance, workshare arrangements, (iv) other indebtedness with respect to reimbursement-type obligations regarding workers compensation claims, (v) customary performance bonds, bid bonds, appeal bonds, surety bonds, customs bonds, government bonds, performance and completion guarantees and similar obligations (vi) customary indemnification obligations to purchasers in connection with asset sales, (vii) netting services, (viii) overdraft protections, (ix) business credit cards, (x) purchasing cards, (xi) payment processing, (xii) automatic clearinghouse arrangements, (xiii) arrangements in respect of pooled deposit or sweep accounts, (xiv) check endorsement guarantees, and (xv) otherwise in connection with deposit accounts or cash management services;

(j) any judgement Lien or Liens arising from decrees or attachments;

(k) Liens arising from precautionary UCC financing statement filings regarding operating leases of personal property and consignment arrangements;

(l) Liens securing Permitted Senior Debt with a Permitted Senior Lender that has executed and delivered an Acceptable Intercreditor Agreement;

(m) Permitted Licensing Agreements;

(n) Liens solely on any cash earnest money deposits or customary cash escrow arrangements in connection with any letter of intent or purchase agreement in respect of an acquisition or other investment;

(o) Liens arising out of any sale-leaseback transaction, so long as such Liens attach only to the property sold and being leased in such transaction and any accessions and additions thereto or proceeds and products thereof and related property;

(p) Liens of sellers of goods arising under Article 2 of the UCC or otherwise, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(q) any Lien arising under conditional sale, title retention, consignment or similar arrangements for the sale of goods; provided, that such Lien attaches only to the goods subject to such sale, title retention, consignment or similar arrangement; and

(r) Liens in connection with any renewals, extensions and replacements of any of the foregoing.

1.35 "**Permitted Licensing Agreement**" shall mean (a) licenses of off-the-shelf software that is commercially available to the public, (b) intercompany licenses or grants of rights for development, manufacture, commercialization, marketing, promotion, co-promotion, sales or distribution of any Purchased Product, (c) each license agreement existing as of the date hereof and (d) any in-bound or out-bound license granted for the use of Purchased Intellectual Property (as defined in the APA) or any other intellectual property included in the Collateral for the development, manufacture, commercialization, marketing, promotion, co-promotion, sales or distribution of any Purchased Product or otherwise, in each case, on behalf of Crystalys.

1.36 "**Permitted Senior Debt**" means any indebtedness incurred by Crystalys from a Permitted Senior Lender.

1.37 "**Permitted Senior Lender**" means any bona fide lender, which (for the avoidance of doubt) shall be a bank, commercial finance lender or other lending institution regularly engaged in the business of lending money (excluding any Affiliates of the Parties, venture capital, investment banking or other institutions that sometimes engage in lending activities but which are primarily engaged in investments in equity securities or some business other than money lending).

1.38 "**Person**" means any individual, corporation, general or limited partnership, joint venture, limited liability company, estate, trust, association, other business or investment entity or unincorporated organization, or any Governmental Authority.

1.39 "**Prime Rate**" means the prime rate published by The Wall Street Journal, from time to time, as the prime rate.

1.40 "**Purchased Intellectual Property**" has the meaning set forth in the APA.

1.41 "**Purchased Product**" means (a) any pharmaceutical preparation, in any dosage form, formulation, presentation or package configuration containing or comprising, in part or in whole, the Compound, and/or (b) any Licensed Product (as defined in the Fuji License Agreement).

1.42 "**Receiving Party**" has the meaning set forth in Section 6.1.

1.43 "**Regulatory Approval**" means any approval, product and/or establishment licenses, registrations, or authorizations of any federal, state, or local regulatory agency, department, bureau, or other governmental entity, that is necessary for the commercial manufacture, use, storage, import, export, transport, Commercialization, and sale of a Purchased Product in a country in the Territory, including, but not limited to, NDA, MAA, and pricing and national medical insurance program listings and applications, amendments, or supplements underlying any such procedures.

1.44 "**Regulatory Authority**" means any national, federal, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority whose review and/or approval is necessary for the manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of pharmaceutical or biological products in a given country or regulatory jurisdiction.

1.45 "**Representative**" means, with respect to any Person, (a) any direct or indirect member or partner of such Person and (b) any manager, director, trustee, officer, employee, agent, advisor or other representative (including attorneys, accountants, consultants, contractors, actual and potential lenders, investors, co-investors and assignees, bankers and financial advisers) of such Person.

1.46 "**Royalty Interest**" means an undivided percentage ownership interest, in a percentage equal to three percent (3%) of all Net Sales in the Territory during the Royalty Term.

1.47 "**Royalty Interest Right**" means all of Crystalys's right, title and interest in and to the Royalty Interest and all proceeds thereof.

1.48 "**Royalty Payment**" means, for each Fiscal Quarter, an amount payable to Urica with respect to the Royalty Interest equal to three percent (3%) of all Net Sales in the Territory for such Fiscal Quarter.

1.49 "**Royalty Term**" means, with respect to the commercial sale of a Purchased Product in a country in the Territory, on a Purchased Product-by-Purchased Product and country-by-country basis, the period beginning

from the First Commercial Sale Date of such Purchased Product in such country until the latest of: (i) the expiry of the last-to-expire patent right within the Seller Intellectual Property (as defined in the APA) containing a valid claim covering such Purchased Product in such country; (ii) the expiration of regulatory exclusivity rights pertaining to such Purchased Product in such country; and (iii) ten (10) years after the First Commercial Sale Date of such Purchased Product in such country.

1.50 "**Selling Party**" has the meaning set forth in Section 1.30.

1.51 "**Specified Account**" has the meaning set forth in Section 5.2(a).

1.52 "**Tax Action**" means, with respect to a Party, any (a) redomiciliation, reincorporation or other action resulting in a change in tax residence of such Party, its assignee or any Person making a payment on behalf of such Party, or the formation of a branch of any such Party or Person in a jurisdiction other than the United States, but only to the extent that a payment under this Agreement is made by such branch, (b) assignment, delegation or other transfer of this Agreement or all or any portion of such Party's rights and obligations hereunder (including, for sake of clarification, the assignment or delegation of any payment obligations under this Agreement) to another Person after the date hereof, including pursuant to Section 8.10 or (c) adoption of a tax reporting position that amounts are required to be deducted or withheld with respect to payments made to the other Party under this Agreement (other than (i) as a result of a change in Law after the Effective Date, or (ii) pursuant to a "determination" within the meaning of Section 1313 of the Code (or any equivalent under non-U.S. law).

1.53 "**Territory**" means the United States, the European Union (consisting of the countries in the European Union as of the date of the Second Amendment to the Fuji License Agreement), the United Kingdom, Canada, Algeria, Armenia, Azerbaijan, Bahrain, Djibouti, Egypt, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Malta, Morocco, Oman, Qatar, Saudi Arabia, Tunisia, Turkey, United Arab Emirates, West Bank, Yemen and any other jurisdiction contemplated by the Fuji License Agreement.

1.54 "**Third Party**" means any Person other than: (a) Crystalys; (b) Urica; or (c) an Affiliate of the Parties.

## 2. TRANSFER OF THE ROYALTY INTEREST; SECURITY INTEREST

2.1 **Royalty Interest Right**. At the Closing (as defined in the APA) and upon the terms and subject to the conditions of this Agreement, as partial consideration for the purchase of the Acquired Assets, Crystalys hereby agrees to transfer, assign and convey to Urica, and Urica agrees to acquire and accept from Crystalys, the Royalty Interest Right, free and clear of all Liens (other than Permitted Liens).

2.2 **No Assumed Obligations**. Notwithstanding any provision in this Agreement to the contrary, Urica is only agreeing, on the terms and conditions set forth in this Agreement, to acquire and accept the Royalty Interest Right and is not assuming any liability or obligation of Crystalys of whatever nature, whether presently in existence or arising or asserted hereafter. Except as specifically set forth herein in respect of the Royalty Interest Right acquired and accepted hereunder, Urica does not, by such acquisition and acceptance, acquire any other rights of Crystalys or any other assets of Crystalys.

2.3 **True Sale**. It is the intention of the Parties hereto that the transfer, assignment and conveyance of the Royalty Interest as contemplated by this Agreement constitute partial consideration to Urica in a sale of the Acquired Assets by Urica to Crystalys and not a financing transaction, borrowing or loan. Accordingly, each of the Parties shall treat the sale, transfer, assignment and conveyance of the Royalty Interest as a sale of an "account" or a "payment intangible" (as appropriate) in accordance with the UCC, and Crystalys hereby authorizes Urica to file financing statements (and continuation statements with respect to such financing statements when applicable) naming Crystalys as the debtor and Urica as the secured party in respect of the Royalty Interest Right.

2.4 In connection with the incurrence by Crystalys of any Permitted Senior Debt, upon the written request of the Permitted Senior Lender, Urica shall enter into an Acceptable Intercreditor Agreement with the Permitted Senior Lender.

2.5 Upon the consummation of any Permitted Senior Debt, all Liens on the Specified Account shall automatically be released and the DACA shall be terminated.

2.6 On the Lien Release Trigger Date, all Liens on the Collateral shall be released in accordance with the Security Agreement.

2.7 Upon the Lien Release Trigger Date and the written request of Crystalys, Urica shall, at the expense of the applicable Obligor, execute and deliver to and authorize the filing by any Obligor all documents such Obligor shall reasonably request to evidence such termination and release (including, without limitation, UCC-3 amendment and termination statements, control agreement terminations (including with respect to the DACA) and USPTO releases).

**3. CLOSING**

3.1 **Closing**. The closing hereunder will take place remotely and simultaneously with the Closing under the APA and will be effective for tax, accounting and all other purposes at the time specified in the APA on the Closing Date (as defined in the APA).

3.2 **Bill of Sale**. At the Closing, Crystalys shall deliver to Urica a duly executed bill of sale evidencing the transfer, assignment and conveyance of the Royalty Interest Right as partial consideration to Urica in a sale of the Acquired Assets by Urica to Crystalys, in form attached hereto as Exhibit B.

**4. REPRESENTATIONS AND WARRANTIES**

4.1 **By Crystalys**. Crystalys hereby represents and warrants to Urica that, as of the date hereof:

(a) **Existence; Good Standing**. Crystalys is a Delaware corporation duly organized, validly existing and in good standing under the laws of the state of Delaware. Crystalys has all requisite corporate power and authority to own, lease and operate its properties and to carry on its business as is now being conducted.

(b) **Authorization**. Crystalys has all necessary corporate power and authority to (i) execute, deliver and perform its respective obligations under this Agreement and the Security Agreement and to consummate the transactions contemplated hereby and thereby, (ii) grant the Liens and other security interests provided for in the Security Agreement, and (iii) take all other actions incidental to this Agreement and the transactions contemplated hereby, and the execution and delivery of this Agreement and the Security Agreement, the grant of the Liens and other security interests pursuant thereto, and the performance of all of its respective obligations hereunder and thereunder have been duly authorized by Crystalys.

(c) **Enforceability**. This Agreement has been duly executed and delivered by an authorized person of Crystalys and constitutes the valid and binding obligation of Crystalys, enforceable against Crystalys in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) **No Conflicts**. The execution, delivery and performance by Crystalys of this Agreement or the Security Agreement do not and will not (i) contravene or conflict with the organizational documents of Crystalys, (ii) contravene or conflict with or constitute a default under any material provision of any law binding upon or applicable to Crystalys or (iii) contravene or conflict with or constitute a

default under any material contract or other material agreement or Judgment binding upon or applicable to Crystalys (other than any breach, default, violation or conflict that is reasonably likely to prevent Crystalys from performing is obligations under this Agreement or the Security Agreement).

(e) **Consents**. No consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Authority or other Person is required to be done or obtained by Crystalys in connection with (i) the execution and delivery by Crystalys of this Agreement or the Security Agreement, (ii) the performance by Crystalys of its obligations under this Agreement or the Security Agreement, or (iii) the consummation by Crystalys of any of the transactions contemplated by this Agreement or the Security Agreement.

(f) **No Litigation**. There is no action, suit, investigation or proceeding pending or, to the knowledge of Crystalys, threatened before any Governmental Authority to which Crystalys is a party that would, if determined adversely, reasonably be expected to prevent or materially and adversely affect the ability of Crystalys to perform its obligations under this Agreement or the Security Agreement.

(g) **Brokers' Fees**. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Crystalys who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

(h) **Tax Status**. Crystalys is a "United States Person" within the meaning of Section 7701(a)(30) of the Code.

4.2 **By Urica**. Urica hereby represents and warrants to Crystalys that:

(a) **Existence; Good Standing**. Urica is a Delaware corporation duly organized, validly existing and in good standing under the laws of the state of Delaware. Urica has all requisite corporate power and authority to own, lease and operate its properties and to carry on its business as is now being conducted.

(b) **Authorization**. Urica has all necessary corporate power and authority to execute, deliver and perform its respective obligations under this Agreement, the Security Agreement and to consummate the transactions contemplated hereto and thereto, and the execution and delivery of this Agreement and the Security Agreement and the performance of all of its respective obligations hereunder and thereunder have been duly authorized by Urica.

(c) **Enforceability**. This Agreement has been duly executed and delivered by an authorized person of Urica and constitutes the valid and binding obligation of Urica, enforceable against Urica in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) **No Conflicts**. The execution, delivery and performance by Urica of this Agreement or the Security Agreement do not and will not (i) contravene or conflict with the organizational documents of Urica, (ii) contravene or conflict with or constitute a default under any material provision of any law binding upon or applicable to Urica or (iii) contravene or conflict with or constitute a default under any material contract or other material agreement or Judgment binding upon or applicable to Urica (other than any breach, default, violation or conflict that is reasonably likely to prevent Urica from performing is obligations under this Agreement or the Security Agreement).

(e) **Consents**. No consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Authority or other Person is required to be done or obtained by Urica in connection with (i) the execution and delivery by Urica of this Agreement or the Security Agreement, (ii) the performance by Urica of its obligations under this Agreement or the Security Agreement, or (iii) the consummation by Urica of any of the transactions contemplated by this Agreement or the Security Agreement.

(f) **No Litigation**. There is no action, suit, investigation or proceeding pending or, to the knowledge of Urica, threatened before any Governmental Authority to which Urica is a party that would, if determined adversely, reasonably be expected to prevent or materially and adversely affect the ability of Urica to perform its obligations under this Agreement.

(g) **Brokers' Fees**. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Urica who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

(h) **Tax Status**. Urica is a "United States Person" within the meaning of Section 7701(a)(30) of the Code.

4.3 **No Implied Representations and Warranties**. Urica acknowledges and agrees that, other than the express representations and warranties of Crystalys specifically contained in this Article 4 (Representations and Warranties), Section 4 of the Security Agreement or Section 5.1 of the APA, (a) there are no representations or warranties of Crystalys either expressed or implied, at law or in equity, including with respect to the Royalty Payments, merchantability or fitness for any particular purpose, and that Urica does not rely on, and shall have no remedies in respect of, any representation or warranty not specifically set forth in this Article 4 (Representations and Warranties) Section 4 of the Security Agreement or Section 5.1 of the APA, and all other representations and warranties are hereby expressly disclaimed, and (b) nothing contained herein guarantees the aggregate Royalty Payments due to Urica will achieve any specific amounts. Notwithstanding the foregoing, claims for fraud, gross negligence, or willful misconduct shall not be waived or limited in any way by this Section 4.3 (No Implied Representations and Warranties). Except for the Royalty Interest Right, Urica further acknowledges and agrees that no licenses or assignments under any assets of Crystalys or its Affiliates are granted pursuant to this Agreement, including by implication, estoppel, exhaustion or otherwise.

## 5. COVENANTS

5.1 **Diligence and Other Covenants**.

(a) Crystalys shall use Commercially Reasonable Efforts to develop, obtain Regulatory Approval (as defined in the APA) for, and commercialize a pharmaceutical product in any dosage or form or formulation that contains or comprises the Compound and/or constitutes a Licensed Product (as defined in the Fuji License Agreement in effect as of the Effective Date).

(b) Crystalys shall use Commercially Reasonable Efforts to (i) maintain the Fuji License Agreement in good standing and (ii) not take any action that could result (i) in the breach of or a default under Fuji License Agreement, or (ii) in the failure of the Fuji License Agreement to be a legal, valid and binding obligation of Crystalys, enforceable against Crystalys in accordance with its terms, except as enforceability may be limited or affected by applicable bankruptcy, insolvency, moratorium, reorganization or other laws of general application relating to or affecting creditors' rights generally. For avoidance of doubt, it would be commercially reasonable for Crystalys to terminate the Fuji License Agreement if it is not developing, manufacturing or commercializing the Purchased Product.

(c) In the event that Crystalys licenses or sublicenses the Purchase Product, Crystalys shall cause the license with such licensee or sub-licensee to include a net sales or similar concept provision that is calculated substantially in accordance with Net Sales.

5.2 **Royalty**.

(a) **Royalty Payments**. From and after the First Commercial Sale Date, within seventy-five (75) days after the end of each Fiscal Quarter during the Royalty Term, on a Purchased Product-by-Purchased Product and country-by-country basis, Crystalys shall pay to Urica, without any setoff or offset (subject, in each case, to Section 5.7 (Certain Tax Matters)), the Royalty Payment due from the Net Sales of all Purchased Products in all countries in the Territory for that Fiscal Quarter. All such amounts will be deposited by Crystalys into a deposit account (the "**Specified Account**") that is subject to a "springing control" deposit account control agreement ("**DACA**").

(b) **Reports**. Within seventy-five (75) days after the end of each Fiscal Quarter during the Term, Crystalys shall provide Urica with a report for the Fiscal Quarter setting forth the Net Sales of the Purchased Product in the applicable Fiscal Quarter on a Purchased Product-by-Purchased Product and country-by-country basis, along with Crystalys's calculation of the Royalty Payments due to Urica during such Fiscal Quarter (the "**Quarterly Report**"). Crystalys shall keep accurate records in sufficient detail to enable to determination of any payment payable under this Agreement. The Quarterly Report shall include, at minimum, the same level of detail and information as provided to Fuji pursuant to the Fuji License Agreement.

(c) **Currency**. All Royalty Payments shall be paid in U.S. Dollars via electronic funds transfer or wire transfer of immediately available funds to such bank account as the other party shall designate in writing prior to the date of such payment. For sales outside of the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in U.S. Dollars will be made at the monthly rate of exchange utilized by Crystalys in its worldwide accounting system. If, due to prohibitions imposed by national or international authorities, payments cannot be made as provided in this Section 5.2 (Royalty), the Parties shall consult with each other to determine a prompt and acceptable solution.

(d) **Late Payment**. A late fee of one percent (1%) over the Prime Rate (calculated on a per annum basis) will accrue on all unpaid amounts with respect to any Royalty Payment from the date such obligation was due. The imposition and payment of a late fee shall not constitute a waiver of Urica's rights with respect to such payment default.

(e) **Audit Right**. During the Royalty Term and for a period of three (3) years thereafter, Urica shall have the right, upon prior written notice to Crystalys, not more than once in any Fiscal Year, to audit the books and records of Crystalys through an independent certified public accounting firm of nationally recognized standing selected by Urica and reasonably acceptable to Crystalys. The independent certified public accountant shall execute a confidentiality agreement, in a form reasonably acceptable to Crystalys, with respect to all information provided by Crystalys. Crystalys shall grant the independent ceritifed public accountant access during normal business hours to the books and records of Crystalys concerning the Purchased Products as may be reasonably necessary for the sole purpose of verifying the accuracy of the reports required to be furnished by Crystalys pursuant to Sections 5.2(b); provided, however, that verification shall not include records for more than the preceding three (3) years. The records and results of the auditors shall be deemed Confidential Information of Crystalys and Urica. A copy of the independent certified public accountant's report shall be delivered to Crystalys simultaneously with its delivery to Urica. If the independent certified public accountant's report correctly shows any underpayment of royalties by

Crystalys, Crystalys shall remit to Urica within thirty (30) days after Crystalys' receipt of such report: (i) the amount of the underpayment; (ii) interest on the underpayment that shall be calculated pursuant to Section 5.2(d); and (iii) the reasonable fees and expenses of the independent certified public accountant performing the audit if and only if the underpayment exceeds the greater of five percent (5%) or Fifty Thousand U.S. dollars ($50,000) of the total Royalty Payment owed for the Fiscal Year then being reviewed. Otherwise, Urica's accountant fees and expenses will be borne by Urica. If the independent certified public accountant's report correctly shows any overpayment of royalties by Crystalys, Urica shall remit to Crystalys within thirty (30) days after Urica' receipt of such report the amount of the overpayment. In the event that an independent certified public accountant appointed by Fuji delivers a report to Crystalys showing any underpayment of royalties by Crystalys to Fuji pursuant to Section 9-4 of the Fuji License Agreement, Crystalys shall promptly, but within five (5) Business Days of receiving a copy of such report, provide written notice to Urica that Crystalys is in receipt of such report, and following receipt of such notice, Urica may invoke its audit rights pursuant to this Section 5.2(e). Notwithstanding anything in this Agreement to the contrary, Crystalys shall keep, or cause to be kept, records of the sales of the Purchased Products under this Agreement for a period of three (3) years after the expiration of each Fiscal Year. Upon reasonable request by Urica, Crystalys shall supply Urica with those records, which may be submitted to an applicable tax authority, and Crystalys shall give Urica commercially reasonable assistance in relation thereto.

5.3 **Change of Control and Divestitures**. In the event of (a) a Change of Control of Crystalys, or (b) a sale, assignment, exclusively license, transfer, lease, conveyance or other disposition by Crystalys to another Person of all or any part of the Collateral (including, without limitation, the Acquired Assets (as defined in the APA) that are primarily related to the Compound or the Purchased Product) (such Collateral or portion thereof, the "**Transferred Assets**", such Change of Control or other transaction, a "**Divestiture**" and the party receiving such Transferred Assets or the acquiror(s) in such Change of Control, the "**Transferee**"), Crystalys shall (i) provide Urica at least thirty (30) days prior written notice of each and every proposed Divestiture, (ii) prior to or contemporaneously with the consummation of each and every Divestiture, cause each applicable Transferee to acknowledge and expressly agree in writing with, *inter alios*, Urica (in forms substantially similar to this Agreement, the Intercreditor Agreement and the Security Agreement) to assume the same obligations that Crystalys, its Affiliates and its permitted successors and assigns have under this Agreement, the Intercreditor Agreement and the Security Agreement, including (without limitation) those obligations with respect to the payment of the Royalty Payments pursuant to Section 5.2, and such obligations under this Agreement, the Intercreditor Agreement and the Security Agreement shall apply, *mutatis mutandis*, to such Transferee, and (iii) prior to or contemporaneously with the consummation of each and every Divestiture, cause all secured creditors of each applicable Transferee that would have a Lien on any of the Transferred Assets to expressly agree in writing with, *inter alios*, Urica (in form substantially similar to the Intercreditor Agreement) to assume the same obligations of a Permitted Senior Lender under the Intercreditor Agreement, which obligations shall apply, *mutatis mutandis*, to such secured creditor(s). For the avoidance of doubt, after any such Divestiture conducted in compliance with the foregoing in this Section 5.3, Crystalys shall no longer be liable to Urica for the Royalty Payments and its other obligations under this Agreement, the Intercreditor Agreement and the Security Agreement.

5.4 **Disclosures**. Neither Party shall, and each Party hereto shall cause its respective Representatives, Affiliates and Affiliates' Representatives not to, issue a press release or other public announcement or otherwise make any public disclosure with respect to this Agreement, or the subject matter hereof, without the prior written consent of the other Party hereto (which consent shall not be unreasonably withheld or delayed), except as may be required by applicable Law, the UCC or stock exchange rule (in which case the party hereto required to make the press release or other public announcement or disclosure shall allow the other party hereto reasonable time to comment on, and, if applicable, reasonably request the disclosing party to seek to the extent available confidential

treatment in respect of portions of, such press release or other public announcement or disclosure in advance of such issuance).

5.5 **Efforts to Consummate Transactions**. Subject to the terms and conditions of this Agreement, each of Crystalys and Urica shall use its commercially reasonable efforts prior to the Closing to take, or cause to be taken, all actions and to do, or cause to be done, all things reasonably necessary under applicable Law to consummate the transactions contemplated by this Agreement and the Security Agreement. Each of Urica and Crystalys agrees to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement and the Security Agreement.

5.6 **Further Assurances**. Following the Closing, Crystalys and Urica agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to give effect to the transactions contemplated by this Agreement and the Security Agreement.

5.7 **Certain Tax Matters**.

(a) The Parties agree that for tax purposes, the Royalty Payments from Crystalys to Urica pursuant to Section 5.2 (Royalty) shall be treated under current law as deferred contingent consideration for the sale of the Acquired Assets by Urica to Crystalys eligible for installment sale treatment under Section 453 of the Code and any corresponding provision of foreign, state or local law, as appropriate. Each Party agrees not to take any position that is inconsistent with the provisions of this Section 5.7(a) on any tax return or in any audit or other tax-related administrative or judicial proceeding unless the other Party has consented in writing (such consent not to be unreasonably withheld, conditioned or delayed) to such actions or as otherwise required by a change in Law after the Effective Date or a "determination" within the meaning of Section 1313(a) of the Code. If there is an inquiry by any Governmental Authority of a Party related to the treatment described in this Section 5.7(a), the Parties hereto shall reasonably cooperate with each other in responding to such inquiry in a reasonable manner which is consistent with this Section 5.7(a).

(b) Crystalys shall be entitled to deduct or withhold from any payment to Urica or any Affiliate of Urica pursuant to this Agreement such amounts as Crystalys is required to deduct or withhold therefrom under the Code, or any applicable Law, with respect to the making of such payment; provided, that Crystalys shall notify Urica at least five (5) Business Days prior to deducting and withholding from any amounts otherwise payable pursuant to this Agreement, which notice shall include the authority, basis and method of calculation for the proposed deduction or withholding, and shall use commercially reasonable efforts to cooperate with Urica to reduce or eliminate any such deduction or withholding. To the extent that such amounts are so deducted or withheld and, if applicable, paid to the appropriate Governmental Authority, and subject to Section 5.7(d), such amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction or withholding was made.

(c) Subject to Section 5.7(d), each Party shall be responsible for all taxes imposed on such Party relating to the transactions and any amounts paid to such Party in connection with this Agreement. The Parties agree that all amounts payable under Section 5.2 (Royalty) are exclusive of all applicable federal, national, state and local sales and use taxes, value added taxes, goods and services taxes, excise taxes or similar taxes imposed with respect to such payments (such taxes, "**Indirect Taxes**"), which shall be the responsibility of Crystalys. For the avoidance of doubt, such Indirect Taxes shall not include any income taxes. The Parties shall reasonably cooperate in accordance with applicable Law to minimize any Indirect Taxes incurred in connection with the transactions contemplated by this Agreement.

(d) Notwithstanding anything to the contrary in this Agreement, in the event any Party, Transferee or licensee or sub-licensee of such Party takes any Tax Action without the other Party's prior written consent and, as a result thereof, the amount of taxes required to be deducted or withheld in respect of a payment to the other Party (the "**Non-Acting Party**" and such taxes, "**Withholding Taxes**") is greater than the amount of Withholding Taxes that would have been required to be withheld absent such Tax Action, then the amount payable to the Non-Acting Party shall be adjusted to take into account such additional Withholding Taxes as necessary so that, after making all required withholdings, the Non-Acting Party receives an amount equal to the sum it would have received had no such Tax Action been taken. The obligation to adjust payments pursuant to the preceding sentence shall not apply, however, to the extent such increased Withholding Tax would not have been imposed but for a Tax Action taken by the Non-Acting Party pursuant to the preceding sentence.

## 6. CONFIDENTIALITY

6.1 **Confidentiality**. Except as provided in this Article 6 (Confidentiality) or otherwise agreed in writing by the Parties, the Parties hereto agree that, during the term of this Agreement and for five (5) years thereafter, each Party (the "**Receiving Party**") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any information furnished to it by or on behalf of the other party (the "**Disclosing Party**") pursuant to this Agreement (such information, "**Confidential Information**" of the Disclosing Party), except for that portion of such information that:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement or any other agreement;

(d) is independently developed by the Receiving Party or any of its Affiliates, as evidenced by written records, without the use of or reference of the Confidential Information; or

(e) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party without obligations of confidentiality with respect thereto.

6.2 **Authorized Disclosure**. Either Party may disclose Confidential Information to the extent such disclosure is reasonably necessary in the following situations: (a) prosecuting or defending litigation; (b) complying with applicable laws and regulations, including regulations promulgated by securities exchanges or pursuant to the UCC; (c) complying with a valid order of a court of competent jurisdiction or other Governmental Authority; (d) for regulatory, tax or customs purposes; (e) for audit purposes, provided that each recipient of Confidential Information must be bound by customary and reasonable obligations of confidentiality and non-use prior to any such disclosure; (f) disclosure to its Affiliates and Representatives on a need-to-know basis, provided that each such recipient of Confidential Information must be bound by contractual or professional obligations of confidentiality and non-use at least as stringent as those imposed upon the parties hereunder prior to any such disclosure; (g) upon the prior written consent of the Disclosing Party; (h) disclosure to its potential investors, and other sources of funding, including equity or debt financing, or potential partners, collaborators or acquirers, and their respective accountants, financial advisors and other professional representatives, provided, that such disclosure shall be made only to the extent customarily required to consummate such investment, financing transaction partnership,

collaboration or acquisition and that each recipient of Confidential Information must be bound by customary obligations of confidentiality and non-use prior to any such disclosure; or (i) as is necessary in connection with a permitted assignment pursuant to Section 8.10 (Assignment). Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 6.2(a)-(d), it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure and use reasonable efforts to secure confidential treatment of such information. In any event, Urica shall not file any patent application, or assist or permit any Person to file any patent application, based upon or using the Confidential Information of Crystalys provided hereunder. Each Party will be permitted to retain (but not use) one file copy of all confidential information on a confidential basis to evidence the scope of and to enforce the Party's obligation of confidentiality and all back up electronic media maintained in the ordinary course of business for archival purposes; provided, however, that, notwithstanding anything to the contrary herein, the confidentiality obligations herein continue for as long as a Party retains any such confidential information.

6.3 **Confidential Information Exchanged Prior to the Effective Date**. All confidential information exchanged between the Parties and their respective Affiliates prior to the effective date of this Agreement (including all confidential information exchanged under the Confidentiality Agreement between Urica and [***], dated April 11, 2023 ("**Confidentiality Agreement**")), will be deemed Confidential Information of the disclosing party as if disclosed hereunder and will be subject to the terms of this Agreement.

## 7. TERMINATION; SURVIVAL

7.1 **Term**. The term of this Agreement will commence on the date hereof, and continue until the earlier to occur of (i) the mutual written agreement of the Parties to terminate this Agreement or (ii) the last to expire Royalty Term for a Purchased Product sold anywhere in the Territory.

7.2 **Survival**. Notwithstanding anything to the contrary in this Article 7 (Termination; Survival), the following provisions shall survive expiration or termination of this Agreement: Article 1 (Definitions), Article 6 (Confidentiality), this Section 7.2 (Survival), and Article 8 (Miscellaneous). Expiration or termination of the Agreement shall not relieve any Party of liability in respect of obligations that accrued under this Agreement, including in respect of any breaches of this Agreement by any Party, on or prior to the effective date of such termination.

## 8. MISCELLANEOUS

8.1 **Entire Agreement; Amendments**. This Agreement, the Security Agreement, the Intercreditor Agreement, together with the other Transaction Documents (as defined in the APA), sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and thereof, and supersedes all prior agreements and understandings between the Parties with respect to the subject matter hereof and thereof, including the Confidentiality Agreement (which will automatically terminate and be of no further force and effect as of the Closing). There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement, the Security Agreement, the Intercreditor Agreement and the other Transaction Documents. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

8.2 **Notices**. Any notice, demand or communication required, permitted or desired to be given hereunder shall be deemed effectively given when personally delivered with signed receipt, when delivered by electronic mail with electronic confirmation of delivery (unless not delivered on a Business Day or delivered after 5:00 p.m. Pacific Time on a Business Day, in which case such delivery shall be deemed effective on the next succeeding Business Day), when delivered by overnight courier with signed receipt, and delivery shall be deemed

effective on the next succeeding Business Day, addressed to the addresses below or to such other address as any Party may designate, with copies thereof to the respective counsel thereof as notified by such Party.

If to Crystalys:

Crystalys Therapeutics, Inc.
100 Pine St. Ste #1250
San Francisco, CA 94111
Email: [***]
Attention: [***]

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92130
Email: cheston.larson@lw.com; dan.vanfleet@lw.com; jekkie.kim@lw.com
Attention: Cheston J. Larson; Dan van Fleet; Jekkie J. Kim

If to Urica:

Urica Therapeutics, Inc.
1111 Kane Concourse, Suite 301
Bay Harbor Islands, FL 33154
Email: legal@fortressbiotech.com
Attention: Legal Department

with a copy (which shall not constitute notice) to:

DLA Piper LLP (US)
Harbor East
650 S. Exeter Street, Suite 1100
Baltimore, Maryland 21202-4576
Email: howard.schwartz@us.dlapiper.com
Attention: Howard S. Schwartz, esq.

8.3 **Severability**. If any of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

8.4 **No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

8.5 **Governing Law**. Resolution of all disputes, controversies or claims arising out of, relating to or in connection with this Agreement or the performance, enforcement, breach or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the state of New York, without regard to conflicts of law rules.

8.6 **Waiver of Jury Trial**. EACH OF THE PARTIES HERETO WAIVES TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. EACH OF THE PARTIES HERETO HEREBY: (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, AND (B) ACKNOWLEDGES THAT IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.6 (Waiver of Jury Trial).

8.7 **Enforcement**. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. Accordingly, each Party shall be entitled to specific performance of the terms hereof, including an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in the state and federal courts located in New York County, New York this being in addition to any other remedy to which such Party is entitled at law or in equity. Each Party hereby further waives (a) any defense in any Proceeding (as defined in the APA) for specific performance that a remedy at law would be adequate and (b) any requirement under any Law to post security or bond as a prerequisite to obtaining equitable relief.

8.8 **Cumulative Remedies**. The rights and remedies provided in this Agreement are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth in this Agreement.

8.9 **No Benefit to Third Parties**. The provisions of this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any Third Party, and no Third Party may seek to enforce, or benefit from, these provisions. The Parties specifically disavow any desire or intention to create any third-party beneficiary hereunder, and specifically declare that no Person, except for the Parties and their successors, shall have any right hereunder nor any right of enforcement hereof.

8.10 **Assignment**. Crystalys may not assign this Agreement, in whole or in part, or any of its rights or obligations hereunder without Urica's prior written consent, provided, however, that Crystalys may assign this Agreement in whole in connection with a Divestiture subject to Section 5.3. Urica may assign this Agreement, in whole or in part, without the prior written consent of Crystalys, including, without limitation in a Change of Control of Urica. This Agreement shall be binding upon, inure to the benefit of and be enforceable by, the Parties hereto and their respective permitted successors and assigns. Any purported assignment in violation of this Section 8.10 (Assignment) shall be null and void.

8.11 **Construction of this Agreement**. When used in this Agreement, the term "including", "include" or "includes" means including, without limiting the generality of any description preceding the term. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). "$" refers to United States Dollars. References to either Party include the successors and permitted assigns of that Party. The headings and table of contents of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. Any reference to a Law includes (a) any regulation or rule promulgated under such Law and (b) any binding interpretation of such Law. Any reference to a Law with respect to a given point in time includes any amendment, modification, or replacement of such Law in effect at such time. The Parties have each consulted counsel of their choice regarding this Agreement and have jointly prepared this Agreement, and, accordingly, no

provisions of this Agreement shall be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. If the terms of this Agreement conflict with the terms of any Exhibit, Schedule, or other Transaction Document, then the terms of this Agreement shall govern solely as to the extent of such conflict unless otherwise expressly stated otherwise. "Exhibit" refers to an exhibit to this Agreement (which, in each case, is incorporated herein by reference), unless otherwise stated in this Agreement. "Schedule" refers to a schedule to this Agreement and incorporates any attachments thereto (which, in each case, are incorporated herein by reference), unless otherwise stated in this Agreement. This Agreement has been prepared in the English language and English shall control its interpretation. Reference to any contract (including this Agreement), document, or instrument shall mean such contract, document, or instrument as amended or modified and in effect from time to time in accordance with the terms thereof and, if applicable, the terms of this Agreement. Reference to any statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. Reference to any period of days shall be deemed to be to the relevant number of calendar days unless otherwise specified. When calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date for calculating such period shall be excluded. If the last day such period is a non-Business Day, the period in question shall end on the next succeeding Business Day. References to articles, sections, clauses, exhibits or schedules shall refer to those portions of this Agreement. The use of the terms "hereunder," "hereof," "hereto," "herein," and words of similar import shall refer to this Agreement as a whole (including the Exhibits and Schedules hereto) and not to any particular article, section, paragraph, or clause of, or exhibit or schedule to, this Agreement unless otherwise indicated. All terms defined in this Agreement have the defined meanings when used in any certificate or other document made or delivered pursuant to this Agreement, unless otherwise defined in such certificate or other document.

8.12 **Relationship of the Parties**. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture or legal entity of any type between the Parties, or to constitute one as the agent of the other. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind or commit the other.

8.13 **Expenses**. Except as otherwise specified in this Agreement, each Party hereto shall pay its own legal, accounting, due diligence, out-of-pocket and other expenses incident to this Agreement and to any action taken by such Party in preparation for carrying this Agreement into effect.

8.14 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute together the same document. Any signature page delivered via any means of electronic communication shall be binding to the same extent as an original signature page.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the Parties have duly executed this Agreement by their proper officers as of the Effective Date.

**URICA THERAPEURTICS, INC.**

By: /s/ Jay Kranzler
Name: Jay Kranzler
Title: Chief Executive Officer

**CRYSTALYS THERAPEUTICS, INC.**

By: /s/ Brian Taylor Slingsby
Name: Brian Taylor Slingsby, MD, PhD, MPH
Title: Chief Executive Officer

**Exhibit A**
**Form of Acceptable Intercreditor Agreement**

**Exhibit B**
**Form of Bill of Sale**

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Lindsay A. Rosenwald, M.D., certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Registrant");

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

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

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

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

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

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

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

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

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

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

Dated: November 14, 2024

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David Jin, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Registrant");

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

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

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

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

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

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

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

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

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

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

Dated: August 14, 2024

By: /s/ David Jin
David Jin
Chief Financial Officer
(Principal Financial Officer)

**Exhibit 32.1**

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

In connection with the Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Company") for the quarterly period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lindsay A. Rosenwald, M.D., Chairman, President, and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my 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.

Dated: November 14, 2024

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, 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 Fortress Biotech, Inc. (the "Company") for the quarterly period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Jin, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my 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.

Dated: November 14, 2024

By: /s/ David Jin
David Jin
Chief Financial Officer
(Principal Financial Officer)