# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D. C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended June 30, 2023**

**or**

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

**Commission File Number: 0-23837**

# Surmodics, Inc.

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

| **MINNESOTA** | **41-1356149** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |

**9924 West 74th Street, Eden Prairie, Minnesota 55344**
**(Address of principal executive offices) (Zip Code)**

**(952) 500-7000**
**(Registrant's telephone number, including area code)**

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

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, $0.05 par value** | **SRDX** | **Nasdaq Global Select Market** |

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

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

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

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

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

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

The number of shares of the registrant's Common Stock, $0.05 par value per share, as of July 28, 2023 was 14,134,000.

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**PART I. FINANCIAL INFORMATION**

Item 1. Unaudited Condensed Consolidated Financial Statements

**Surmodics, Inc. and Subsidiaries**

Condensed Consolidated Balance Sheets

| *(In thousands, except per share data)* | June 30, 2023 | September 30, 2022 |
|---|---|---|
| | *(Unaudited)* | |
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 44,579 | $ 18,998 |
| Accounts receivable, net of allowances of $206 and $81 as of June 30, 2023 and September 30, 2022, respectively | 11,752 | 10,452 |
| Contract assets — royalties and license fees | 7,678 | 7,116 |
| Inventories, net | 14,610 | 11,819 |
| Income tax receivable | — | 2,438 |
| Prepaids and other | 7,231 | 6,764 |
| Total Current Assets | 85,850 | 57,587 |
| Property and equipment, net | 26,571 | 27,148 |
| Intangible assets, net | 27,798 | 28,145 |
| Goodwill | 43,844 | 40,710 |
| Other assets | 4,838 | 4,769 |
| Total Assets | $ 188,901 | $ 158,359 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable | $ 2,484 | $ 3,136 |
| Accrued liabilities: | | |
| Compensation | 7,830 | 8,929 |
| Accrued other | 5,453 | 5,854 |
| Short-term borrowings | — | 10,000 |
| Deferred revenue | 4,328 | 4,160 |
| Income tax payable | 11,953 | — |
| Total Current Liabilities | 32,048 | 32,079 |
| Long-term debt, net | 29,353 | — |
| Deferred revenue, less current portion | 3,492 | 5,088 |
| Deferred income taxes | 2,057 | 2,027 |
| Other long-term liabilities | 9,539 | 10,773 |
| Total Liabilities | 76,489 | 49,967 |
| Commitments and Contingencies (Note 11) | | |
| Stockholders' Equity: | | |
| Series A Preferred stock — $.05 par value, 450 shares authorized; no shares issued and outstanding | — | — |
| Common stock — $.05 par value, 45,000 shares authorized; 14,134 and 14,029 shares issued and outstanding as of June 30, 2023 and September 30, 2022, respectively | 707 | 701 |
| Additional paid-in capital | 34,345 | 28,774 |
| Accumulated other comprehensive loss | (3,201) | (9,874) |
| Retained earnings | 80,561 | 88,791 |
| Total Stockholders' Equity | 112,412 | 108,392 |
| Total Liabilities and Stockholders' Equity | $ 188,901 | $ 158,359 |

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

**Surmodics, Inc. and Subsidiaries**

Condensed Consolidated Statements of Operations

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| *(In thousands, except per share data)* | *(Unaudited)* | | *(Unaudited)* | |
| Revenue: | | | | |
| Product sales | $ 15,667 | $ 13,919 | $ 45,251 | $ 40,227 |
| Royalties and license fees | 34,153 | 8,795 | 52,347 | 26,738 |
| Research, development and other | 2,663 | 2,140 | 7,016 | 6,998 |
| Total revenue | 52,483 | 24,854 | 104,614 | 73,963 |
| Operating costs and expenses: | | | | |
| Product costs | 6,921 | 5,141 | 17,926 | 14,745 |
| Research and development | 11,232 | 12,975 | 36,899 | 38,350 |
| Selling, general and administrative | 12,874 | 12,854 | 39,077 | 33,159 |
| Acquired intangible asset amortization | 879 | 1,024 | 2,659 | 3,184 |
| Restructuring expense | — | — | 1,282 | — |
| Contingent consideration (gain) expense | (835) | 3 | (829) | 9 |
| Total operating costs and expenses | 31,071 | 31,997 | 97,014 | 89,447 |
| Operating income (loss) | 21,412 | (7,143) | 7,600 | (15,484) |
| Other expense: | | | | |
| Interest expense, net | (884) | (145) | (2,594) | (410) |
| Foreign exchange (loss) gain | (61) | 85 | (261) | 120 |
| Investment income, net | 182 | 22 | 531 | 73 |
| Other expense | (763) | (38) | (2,324) | (217) |
| Income (loss) before income taxes | 20,649 | (7,181) | 5,276 | (15,701) |
| Income tax (expense) benefit | (13,303) | 1,530 | (13,506) | 3,155 |
| Net income (loss) | $ 7,346 | $ (5,651) | $ (8,230) | $ (12,546) |
| | | | | |
| Basic net income (loss) per share | $ 0.52 | $ (0.41) | $ (0.59) | $ (0.90) |
| Diluted net income (loss) per share | $ 0.52 | $ (0.41) | $ (0.59) | $ (0.90) |
| | | | | |
| Weighted average number of shares outstanding: | | | | |
| Basic | 14,050 | 13,929 | 14,020 | 13,907 |
| Diluted | 14,072 | 13,929 | 14,020 | 13,907 |

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

**Surmodics, Inc. and Subsidiaries**

Condensed Consolidated Statements of Comprehensive Income (Loss)

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| *(In thousands)* | *(Unaudited)* | | *(Unaudited)* | |
| Net income (loss) | $ 7,346 | $ (5,651) | $ (8,230) | $ (12,546) |
| Other comprehensive income (loss): | | | | |
| Derivative instruments: | | | | |
| Unrealized net gain (loss) | 607 | — | (141) | — |
| Net (gain) loss reclassified to earnings | (39) | — | (19) | — |
| Net changes related to available-for-sale securities, net of tax | — | 4 | — | (7) |
| Foreign currency translation adjustments | 45 | (4,289) | 6,833 | (7,439) |
| Other comprehensive income (loss) | 613 | (4,285) | 6,673 | (7,446) |
| Comprehensive income (loss) | $ 7,959 | $ (9,936) | $ (1,557) | $ (19,992) |

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

**Surmodics, Inc. and Subsidiaries**

Condensed Consolidated Statements of Stockholders' Equity

| | Three Months Ended June 30, 2023 and 2022 | | | | | |
|---|---|---|---|---|---|---|
| | *(Unaudited)* | | | | | |
| | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive | Retained | Total Stockholders' |
| *(In thousands)* | Shares | Amount | Capital | Loss | Earnings | Equity |
| **Balance at March 31, 2023** | 14,134 | $ 707 | $ 32,446 | $ (3,814) | $ 73,215 | $ 102,554 |
| Net income | — | — | — | — | 7,346 | 7,346 |
| Other comprehensive income, net of tax | — | — | — | 613 | — | 613 |
| Issuance of common stock | 1 | — | — | — | — | — |
| Common stock options exercised, net | — | — | — | — | — | — |
| Purchase of common stock to pay employee taxes | (1) | — | (16) | — | — | (16) |
| Stock-based compensation | — | — | 1,915 | — | — | 1,915 |
| **Balance at June 30, 2023** | 14,134 | $ 707 | $ 34,345 | $ (3,201) | $ 80,561 | $ 112,412 |
| | | | | | | |
| **Balance at March 31, 2022** | 13,990 | $ 700 | $ 24,827 | $ (1,434) | $ 109,170 | $ 133,263 |
| Net loss | — | — | — | — | (5,651) | (5,651) |
| Other comprehensive loss, net of tax | — | — | — | (4,285) | — | (4,285) |
| Issuance of common stock | 9 | — | — | — | — | — |
| Common stock options exercised, net | 1 | — | 22 | — | — | 22 |
| Purchase of common stock to pay employee taxes | (1) | — | (36) | — | — | (36) |
| Stock-based compensation | — | — | 1,799 | — | — | 1,799 |
| **Balance at June 30, 2022** | 13,999 | $ 700 | $ 26,612 | $ (5,719) | $ 103,519 | $ 125,112 |

| | Nine Months Ended June 30, 2023 and 2022 | | | | | |
|---|---|---|---|---|---|---|
| | *(Unaudited)* | | | | | |
| | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive | Retained | Total Stockholders' |
| *(In thousands)* | Shares | Amount | Capital | (Loss) Income | Earnings | Equity |
| **Balance at September 30, 2022** | 14,029 | $ 701 | $ 28,774 | $ (9,874) | $ 88,791 | $ 108,392 |
| Net loss | — | — | — | — | (8,230) | (8,230) |
| Other comprehensive income, net of tax | — | — | — | 6,673 | — | 6,673 |
| Issuance of common stock | 113 | 6 | 447 | — | — | 453 |
| Common stock options exercised, net | 17 | 1 | 349 | — | — | 350 |
| Purchase of common stock to pay employee taxes | (25) | (1) | (887) | — | — | (888) |
| Stock-based compensation | — | — | 5,662 | — | — | 5,662 |
| **Balance at June 30, 2023** | 14,134 | $ 707 | $ 34,345 | $ (3,201) | $ 80,561 | $ 112,412 |
| | | | | | | |
| **Balance at September 30, 2021** | 13,899 | $ 695 | $ 21,598 | $ 1,727 | $ 116,065 | $ 140,085 |
| Net loss | — | — | — | — | (12,546) | (12,546) |
| Other comprehensive loss, net of tax | — | — | — | (7,446) | — | (7,446) |
| Issuance of common stock | 100 | 5 | 367 | — | — | 372 |
| Common stock options exercised, net | 21 | 1 | 390 | — | — | 391 |
| Purchase of common stock to pay employee taxes | (21) | (1) | (941) | — | — | (942) |
| Stock-based compensation | — | — | 5,198 | — | — | 5,198 |
| **Balance at June 30, 2022** | 13,999 | $ 700 | $ 26,612 | $ (5,719) | $ 103,519 | $ 125,112 |

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

**Surmodics, Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows

| | Nine Months Ended June 30, | |
|---|---|---|
| | 2023 | 2022 |
| *(In thousands)* | *(Unaudited)* | |
| Operating Activities: | | |
| Net loss | $ (8,230) | $ (12,546) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization | 6,365 | 6,902 |
| Stock-based compensation | 5,662 | 5,198 |
| Noncash lease expense | 485 | 371 |
| Amortization of debt issuance costs | 274 | 34 |
| Provision for credit losses | 163 | 8 |
| Contingent consideration (gain) expense | (829) | 9 |
| Deferred taxes | (187) | (2,996) |
| Other | 124 | 214 |
| Change in operating assets and liabilities: | | |
| Accounts receivable and contract assets | (1,825) | (847) |
| Inventories | (2,790) | (4,167) |
| Prepaids and other | (961) | (1,998) |
| Accounts payable | (669) | 349 |
| Accrued liabilities | (2,474) | (1,039) |
| Income taxes | 15,583 | (676) |
| Deferred revenue | (1,427) | (3,539) |
| Net cash provided by (used in) operating activities | 9,264 | (14,723) |
| Investing Activities: | | |
| Purchases of property and equipment | (2,170) | (2,798) |
| Maturities of available-for-sale securities | — | 7,600 |
| Net cash (used in) provided by investing activities | (2,170) | 4,802 |
| Financing Activities: | | |
| Payments of short-term borrowings | (10,000) | — |
| Proceeds from issuance of long-term debt | 29,664 | — |
| Payments of debt issuance costs | (614) | — |
| Issuance of common stock | 803 | 763 |
| Payments for taxes related to net share settlement of equity awards | (888) | (936) |
| Payments for acquisition of in-process research and development | (978) | (500) |
| Net cash provided by (used in) financing activities | 17,987 | (673) |
| Effect of exchange rate changes on cash | 500 | (485) |
| Net change in cash and cash equivalents | 25,581 | (11,079) |
| Cash and Cash Equivalents: | | |
| Beginning of period | 18,998 | 31,153 |
| End of period | $ 44,579 | $ 20,074 |
| Supplemental Information: | | |
| Cash paid for income taxes | $ 251 | $ 395 |
| Cash paid for interest | 2,157 | 256 |
| Noncash investing and financing activities: | | |
| Acquisition of property and equipment, net of refundable credits in other current assets and liabilities | — | 90 |
| Right-of-use assets obtained in exchange for new operating lease liabilities | — | 1,732 |

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

**Surmodics, Inc. and Subsidiaries**
**Notes to Condensed Consolidated Financial Statements**
**Period Ended June 30, 2023**
**(Unaudited)**

## 1. Organization

***Description of Business***

Surmodics, Inc. and subsidiaries (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms) is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic ("IVD") immunoassay tests and microarrays. Surmodics develops and commercializes highly differentiated vascular intervention medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The Company's mission is to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

***Basis of Presentation and Principles of Consolidation***

The accompanying unaudited condensed consolidated financial statements include all accounts and wholly-owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"). All intercompany transactions have been eliminated. The Company operates on a fiscal year ending on September 30. In accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited consolidated financial statements of the Company. These unaudited condensed consolidated financial statements should be read together with the audited consolidated financial statements for the fiscal year ended September 30, 2022, and notes thereto included in our Annual Report on Form 10-K as filed with the SEC.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Ultimate results could differ from those estimates. The results of operations for the three and nine months ended June 30, 2023 are not necessarily indicative of the results that may be expected for the entire 2023 fiscal year.

Certain reclassifications have been made to the prior year's consolidated financial statements to conform to the current year presentation.

***New Accounting Pronouncements***

No new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company's condensed consolidated financial statements.

**2. Revenue**

The following table presents the Company's revenues disaggregated by product classification and by reportable segment.

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| *(In thousands)* | 2023 | 2022 | 2023 | 2022 |
| **Medical Device** | | | | |
| Product sales | $ 9,299 | $ 6,741 | $ 25,593 | $ 19,970 |
| Royalties | 8,220 | 7,771 | 23,702 | 23,015 |
| License fees | 25,933 | 1,024 | 28,645 | 3,723 |
| Research, development and other | 2,562 | 1,992 | 6,799 | 6,181 |
| Medical Device Revenue | 46,014 | 17,528 | 84,739 | 52,889 |
| **In Vitro Diagnostics** | | | | |
| Product sales | 6,368 | 7,178 | 19,658 | 20,257 |
| Research, development and other | 101 | 148 | 217 | 817 |
| In Vitro Diagnostics Revenue | 6,469 | 7,326 | 19,875 | 21,074 |
| **Total Revenue** | $ 52,483 | $ 24,854 | $ 104,614 | $ 73,963 |

Contract assets totaled $7.7 million and $7.1 million as of June 30, 2023 and September 30, 2022, respectively, on the condensed consolidated balance sheets. Fluctuations in the balance of contract assets result primarily from changes in sales-based and minimum royalties earned, but not collected, at each balance sheet date due to payment timing and contractual changes in the normal course of business. For discussion of contract liability (deferred revenue) balances and remaining performance obligations, see Note 3 Collaborative Arrangement.

**3. Collaborative Arrangement**

On February 26, 2018, the Company entered into an agreement with Abbott Vascular, Inc. ("Abbott") whereby Abbott has exclusive worldwide commercialization rights for Surmodics' SurVeil™ drug-coated balloon ("DCB") to treat the superficial femoral artery (the "Abbott Agreement"). In June 2023, the Company received premarket approval ("PMA") for the *SurVeil* DCB from the U.S. Food and Drug Administration ("FDA"), and the product may now be marketed and sold in the U.S. by the Company's exclusive distribution partner, Abbott. Under the Abbott Agreement, Abbott has the right to purchase commercial units from Surmodics, and the Company will realize revenue from product sales to Abbott at an agreed-upon transfer price, as well as a share of net profits resulting from third-party product sales by Abbott. Timing of commercialization in the U.S. is at the discretion of Abbott.

Under the Abbott Agreement, Surmodics is responsible for conducting all necessary clinical trials, including completion of the ongoing, five-year TRANSCEND pivotal clinical trial. Abbott and Surmodics participate on a joint development committee charged with providing guidance on the Company's clinical and regulatory activities with regard to the *SurVeil* DCB product.

As of June 30, 2023, the Company had received payments totaling $87.8 million for achievement of clinical and regulatory milestones under the Abbott Agreement, which consisted of the following: (i) $25 million upfront fee in fiscal 2018, (ii) $10 million milestone payment in fiscal 2019, (iii) $10.8 million milestone payment in fiscal 2020, (iv) $15 million milestone payment in fiscal 2021, and (v) $27 million milestone payment in the third quarter of fiscal 2023 upon receipt of PMA for the *SurVeil* DCB from the FDA. As of June 30, 2023, there are no remaining contingent milestone payments under the Abbott Agreement.

License fee revenue recognized from the Abbott Agreement on the condensed consolidated statements of operations totaled $25.9 million and $1.0 million for the three months ended June 30, 2023 and 2022, respectively, and $28.5 million and $3.6 million for the nine months ended June 30, 2023 and 2022, respectively. The amount of revenue recognized from the Abbott Agreement that was included in the respective beginning of fiscal year balances of deferred revenue on the condensed consolidated balance sheets totaled $3.9 million and $3.6 million for the nine months ended June 30, 2023 and 2022, respectively.

As of June 30, 2023 and September 30, 2022, deferred revenue on the condensed consolidated balance sheets included $7.7 million and $9.2 million, respectively, related to payments received under the Abbott Agreement. The $7.7 million in deferred revenue as of June 30, 2023, which represents the Company's performance obligations that are unsatisfied for executed contracts with an original duration of one year, is expected to be recognized as revenue over the next two years through fiscal 2025 as services, principally TRANSCEND clinical trial, are completed.

**4. Fair Value Measurements**

Assets and liabilities measured at fair value on a recurring basis by level of the fair value hierarchy were as follows:

| | June 30, 2023 | | | |
|---|---|---|---|---|
| *(In thousands)* | Quoted Prices in Active Markets for Identical Instruments (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total Fair Value |
| Assets | | | | |
| Cash equivalents (1) | $ — | $ 14,733 | $ — | $ 14,733 |
| Total assets | $ — | $ 14,733 | $ — | $ 14,733 |
| Liabilities | | | | |
| Interest rate swap (2) | — | 160 | — | 160 |
| Total liabilities | $ — | $ 160 | $ — | $ 160 |

| | September 30, 2022 | | | |
|---|---|---|---|---|
| *(In thousands)* | Quoted Prices in Active Markets for Identical Instruments (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total Fair Value |
| Assets | | | | |
| Cash equivalents (1) | $ — | $ 2,035 | $ — | $ 2,035 |
| Total assets | $ — | $ 2,035 | $ — | $ 2,035 |
| Liabilities | | | | |
| Contingent consideration (3) | $ — | $ — | $ 829 | $ 829 |
| Total liabilities | $ — | $ — | $ 829 | $ 829 |

(1) Fair value of cash equivalents (money market funds) is based on quoted vendor prices and broker pricing where all significant inputs are observable.

(2) Fair value of interest rate swap is based on forward-looking, one-month term secured overnight financing rate (“Term SOFR”) spot rates and interest rate curves (Note 7).

(3) Fair value of contingent consideration liabilities was determined based on discounted cash flow analyses that included probability and timing of development and regulatory milestone achievements and a discount rate, which are considered significant unobservable inputs as of September 30, 2022.

Contingent consideration liabilities are remeasured to fair value each reporting period using discount rates, probabilities of payment and projected payment dates. Increases or decreases in the fair value of the contingent consideration liability can result from changes in the timing or likelihood of achieving milestones and changes in discount periods and rates. Projected contingent payment amounts are discounted back to the current period using a discount cash flow model. Interest accretion and fair value adjustments associated with contingent consideration liabilities are reported in contingent consideration (gain) expense on the condensed consolidated statements of operations.

Changes in the contingent consideration liabilities measured at fair value using Level 3 inputs were as follows:

| *(In thousands)* | |
|---|---|
| Contingent consideration liability at September 30, 2022 | $ 829 |
| Additions | — |
| Fair value adjustments | (835) |
| Settlements | — |
| Interest accretion | 6 |
| Foreign currency translation | — |
| Contingent consideration liability at June 30, 2023 | $ — |

Contingent consideration liabilities were associated with the fiscal 2021 acquisition of Vetex Medical Limited ("Vetex") and were included in other long-term liabilities on the condensed consolidated balance sheets as of September 30, 2022.

**5. Supplemental Balance Sheet Information**

***Inventories***

Inventories consisted of the following components:

| *(In thousands)* | June 30, 2023 | September 30, 2022 |
|---|---|---|
| Raw materials | $ 8,274 | $ 6,102 |
| Work-in process | 2,016 | 1,595 |
| Finished products | 4,320 | 4,122 |
| Total | $ 14,610 | $ 11,819 |

***Prepaids and Other Assets, Current***

Prepaids and other current assets consisted of the following:

| *(In thousands)* | June 30, 2023 | September 30, 2022 |
|---|---|---|
| Prepaid expenses | $ 2,961 | $ 2,570 |
| Irish research and development credits receivable | 829 | 753 |
| CARES Act employee retention credit receivable (1) | 3,441 | 3,441 |
| Prepaids and other | $ 7,231 | $ 6,764 |

(1) Receivable consisted of anticipated reimbursement of personnel expenses incurred in fiscal periods prior to fiscal 2023 as a result of our eligibility for the employee retention credit under the provisions of the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”).

***Intangible Assets***

Intangible assets consisted of the following:

| | | June 30, 2023 | | |
|---|---|---|---|---|
| *(Dollars in thousands)* | Weighted Average Original Life (Years) | Gross Carrying Amount | Accumulated Amortization | Net |
| **Definite-lived intangible assets:** | | | | |
| Customer lists and relationships | 8.9 | $ 12,484 | $ (10,386) | $ 2,098 |
| Developed technology | 11.9 | 34,727 | (10,570) | 24,157 |
| Patents and other | 14.1 | 3,551 | (2,588) | 963 |
| Total definite-lived intangible assets | | 50,762 | (23,544) | 27,218 |
| **Unamortized intangible assets:** | | | | |
| Trademarks and trade names | | 580 | — | 580 |
| Total intangible assets | | $ 51,342 | $ (23,544) | $ 27,798 |

| (Dollars in thousands) | Weighted Average Original Life (Years) | September 30, 2022 Gross Carrying Amount | Accumulated Amortization | Net |
|---|---|---|---|---|
| **Definite-lived intangible assets:** | | | | |
| Customer lists and relationships | 8.9 | $ 11,354 | $ (8,827) | $ 2,527 |
| Developed technology | 11.9 | 31,943 | (7,994) | 23,949 |
| Patents and other | 14.1 | 3,551 | (2,462) | 1,089 |
| Total definite-lived intangible assets | | 46,848 | (19,283) | 27,565 |
| **Unamortized intangible assets:** | | | | |
| Trademarks and trade names | | 580 | — | 580 |
| Total intangible assets | | $ 47,428 | $ (19,283) | $ 28,145 |

Intangible asset amortization expense was $0.9 million and $1.1 million for the three months ended June 30, 2023 and 2022, respectively, and $2.9 million and $3.4 million for the nine months ended June 30, 2023 and 2022, respectively. Based on the intangible assets in service as of June 30, 2023, estimated amortization expense for future fiscal years was as follows:

| (In thousands) | |
|---|---|
| Remainder of 2023 | $ 945 |
| 2024 | 3,779 |
| 2025 | 3,743 |
| 2026 | 2,845 |
| 2027 | 2,595 |
| 2028 | 2,584 |
| Thereafter | 10,727 |
| Definite-lived intangible assets | $ 27,218 |

Future amortization amounts presented above are estimates. Actual future amortization expense may be different as a result of future acquisitions, impairments, changes in amortization periods, foreign currency translation rates, or other factors.

***Goodwill***

Changes in the carrying amount of goodwill by segment were as follows:

| (In thousands) | In Vitro Diagnostics | Medical Device | Total |
|---|---|---|---|
| Goodwill as of September 30, 2022 | $ 8,010 | $ 32,700 | $ 40,710 |
| Currency translation adjustment | — | 3,134 | 3,134 |
| Goodwill as of June 30, 2023 | $ 8,010 | $ 35,834 | $ 43,844 |

***Other Assets, Noncurrent***

Other noncurrent assets consisted of the following:

| (In thousands) | June 30, 2023 | September 30, 2022 |
|---|---|---|
| Operating lease right-of-use assets | $ 3,155 | $ 3,633 |
| Other | 1,683 | 1,136 |
| Other assets | $ 4,838 | $ 4,769 |

Other noncurrent assets consisted primarily of prepaid expenses and receivables related to refundable Irish research and development tax credits.

***Accrued Other Liabilities***

Accrued other liabilities consisted of the following:

| *(In thousands)* | June 30, 2023 | September 30, 2022 |
|---|---|---|
| Accrued professional fees | $ 358 | $ 279 |
| Accrued clinical study expense | 1,531 | 1,425 |
| Accrued purchases | 1,203 | 1,655 |
| Acquisition of in-process research and development (1) | 949 | 981 |
| Operating lease liability, current portion | 1,046 | 963 |
| Other | 366 | 551 |
| Total accrued other liabilities | $ 5,453 | $ 5,854 |

(1) Acquisition of in-process research and development consisted of the present value of guaranteed payments to be made (current portion) in connection with an asset acquisition in fiscal 2018 (Note 11).

***Other Long-term Liabilities***

Other long-term liabilities consisted of the following:

| *(In thousands)* | June 30, 2023 | September 30, 2022 |
|---|---|---|
| Deferred consideration (1) | $ 3,447 | $ 4,260 |
| Contingent consideration (2) | — | 829 |
| Unrecognized tax benefits (3) | 3,032 | 1,841 |
| Operating lease liabilities (4) | 3,060 | 3,843 |
| Other long-term liabilities | $ 9,539 | $ 10,773 |

(1) Deferred consideration consisted of the present value of guaranteed payments to be made (noncurrent portion) in connection with the fiscal 2021 Vetex acquisition and with an asset acquisition in fiscal 2018 (Note 11).

(2) Contingent consideration consisted of the fair value of contingent consideration liabilities associated with the fiscal 2021 Vetex acquisition (Note 11).

(3) Balance of unrecognized tax benefits includes accrued interest and penalties, if applicable (Note 10).

(4) Operating lease liabilities consisted of the non-current portion of the net present value of future minimum lease payments, reduced by the discounted value of leasehold improvement incentives paid or payable to the Company.

**6. Debt**

Debt consisted of the following:

| *(In thousands)* | June 30, 2023 | September 30, 2022 |
|---|---|---|
| Short-term borrowings (1) | $ — | $ 10,000 |
| Revolving Credit Facility, Term SOFR + 3.00%, maturing October 1, 2027 | $ 5,000 | $ — |
| Tranche 1 Term Loans, Term SOFR +5.75%, maturing October 1, 2027 | 25,000 | — |
| Long-term debt, gross | 30,000 | — |
| Less: Unamortized debt issuance costs | (647) | — |
| Long-term debt, net | $ 29,353 | $ — |

(1) Consisted of the outstanding balance on the secured revolving credit facility with Bridgewater Bank; this balance was repaid and the credit agreement terminated on October 14, 2022. For further information, refer to the Notes to the Consolidated Financial Statements in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

On October 14, 2022, the Company entered into a secured revolving credit facility and secured term loan facilities pursuant to a Credit, Security and Guaranty Agreement (the "MidCap Credit Agreement") with Mid Cap Funding IV Trust, as agent, and MidCap Financial Trust, as term loan servicer and the lenders from time to time party thereto. The MidCap Credit Agreement provides for availability under a secured revolving line of credit of up to $25.0 million (the "Revolving Credit Facility"). Availability under the Revolving Credit Facility is subject to a borrowing base.

The MidCap Credit Agreement also provides for up to $75.0 million in term loans (the "Term Loans"), consisting of a $25.0 million Tranche 1 ("Tranche 1") and a $50.0 million Tranche 2 ("Tranche 2"), which may be drawn in increments of at least $10.0 million. In addition, after the closing and prior to December 31, 2024, the Term Loan lenders may, in their sole discretion, fund an additional tranche of Term Loans of up to $25.0 million upon the written request of the Company. Upon closing, the Company borrowed $25.0 million of Tranche 1, borrowed $5.0 million on the Revolving Credit Facility, and used approximately $10.0 million of the proceeds to repay borrowings under the revolving credit facility with Bridgewater Bank. The Company intends to use the remaining proceeds to fund working capital needs and for other general corporate purposes, as permitted under the MidCap Credit Agreement. Until December 31, 2024, the Company will be eligible to borrow Tranche 2 at the Company's option upon meeting certain conditions set forth in the MidCap Credit Agreement, including having no less than $60.0 million of rolling-four-quarter core net revenue as of the end of the prior fiscal quarter. Core net revenue is defined in the MidCap Credit Agreement as the sum of revenue from our In Vitro Diagnostics segment and revenues from performance coating technologies in our Medical Device segment.

Pursuant to the MidCap Credit Agreement, the Company provided a first priority security interest in all existing and future acquired assets, including intellectual property and real estate, owned by the Company. The MidCap Credit Agreement contains certain covenants that limit the Company's ability to engage in certain transactions. Subject to certain limited exceptions, these covenants limit the Company's ability to, among other things:

- create, incur, assume or permit to exist any additional indebtedness, or create, incur, allow or permit to exist any additional liens;
- enter into any amendment or other modification of certain agreements;
- effect certain changes in the Company's business, fiscal year, management, entity name or business locations;
- liquidate or dissolve, merge with or into, or consolidate with, any other company;
- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of the Company's capital stock;
- make certain investments, other than limited permitted acquisitions; and
- enter into transactions with the Company's affiliates.

The MidCap Credit Agreement also contains customary indemnification obligations and customary events of default, including, among other things, (i) non-payment, (ii) breach of warranty, (iii) non-performance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (vi) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) termination of a pension plan, (x) regulatory matters, and (xi) material adverse effect.

In addition, the Company must maintain minimum core net revenue levels tested quarterly to the extent that Term Loans advanced under the MidCap Credit Agreement exceed $25.0 million. In the event of default under the MidCap Credit Agreement, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 2%.

Borrowings under the MidCap Credit Agreement bear interest at the forward-looking, one-month secured overnight financing rate ("Term SOFR") as published by CME Group Benchmark Administration Limited plus 0.10% ("Adjusted Term SOFR"). The Revolving Credit Facility bears interest at an annual rate equal to 3.00% plus the greater of Adjusted Term SOFR or 1.50%, and the Term Loans bear interest at an annual rate equal to 5.75% plus the greater of Adjusted Term SOFR or 1.50%. The Company is required to make monthly interest payments on the Revolving Credit Facility with the entire principal payment due at maturity. The Company is required to make 48 monthly interest payments on the Term Loans beginning on November 1, 2022 (the "Interest-Only Period"). If the Company is in covenant compliance at the end of the Interest-Only Period, the Company will have the option to extend the Interest-Only Period through maturity with the entire principal payment due at maturity. If the Company is not in covenant compliance at the end of the Interest-Only Period, the Company is required to make 12 months of straight-line amortization payments with the entire principal amount due at maturity.

Subject to certain limitations, the Term Loans have a prepayment fee for payments made prior to the maturity date equal to 3.0% of the prepaid principal amount for the first year following the closing date of the MidCap Credit Agreement, 2.0% of the prepaid principal amount for the second year following the closing date and 1.0% of the prepaid principal amount for the third year following the closing date and thereafter. In addition, if the Revolving Credit Facility is terminated in whole or in part prior to the maturity date, the Company must pay a prepayment fee equal to 3.0% of the terminated commitment amount for the first year following the closing date of the MidCap Credit Agreement, 2.0% of the terminated commitment amount for the second year following the closing date of the MidCap Credit Agreement and 1.0% of the terminated commitment amount for the third year following the closing date and thereafter. The Company is also required to pay a full exit fee at the time of maturity or full prepayment event equal to 2.5% of the aggregate principal amount of the Term Loans made pursuant to the MidCap Credit Agreement and a partial exit fee at the time of any partial prepayment event equal to 2.5% of the amount prepaid. This exit fee is accreted over the remaining term of the Term Loans. The Company also is obligated to pay customary origination fees at the time of each funding of the Term Loans and a customary annual administrative fee based on the amount borrowed under the Term Loan, due on an annual basis. The customary fees on the Revolving Credit Facility include (i) an origination fee based on the commitment amount, which was paid on the closing date, (ii) an annual collateral management fee of 0.50% per annum based on the outstanding balance of the Revolving Credit Facility, payable monthly in arrears and (iii) an unused line fee of 0.50% per annum based on the average unused portion of the Revolving Credit Facility, payable monthly in arrears. The Company must also maintain a minimum balance of no less than 20% of availability under the Revolving Credit Facility or a minimum balance fee applies of 0.50% per annum. Expenses recognized for fees for the Revolving Credit Facility and Term Loans are reported in interest expense, net on the condensed consolidated statements of operations.

**7. Derivative Financial Instruments**

We periodically enter into interest rate swaps with major financial institutions of high credit quality to mitigate exposure to changes in interest rates on our floating-rate indebtedness. Since the fair value of these interest rate swaps is derived from current market rates, they are classified as derivative financial instruments. We do not use derivatives for speculative or trading purposes.

When the Company has multiple derivative financial instruments with the same counterparty subject to a master netting arrangement, we have elected to offset the amounts: (i) recorded as assets and liabilities and (ii) amounts recognized for the right to reclaim cash collateral we have deposited with the counterparty (i.e., cash collateral receivable). Such offset amounts are presented as either a net asset or liability by counterparty on the condensed consolidated balance sheets.

***Cash Flow Hedge — Interest Rate Swap***

On October 14, 2022, we entered into a floating-to-fixed interest rate swap agreement to mitigate exposure to interest rate increases related to our Term Loans. See Note 6 Debt for further information on our financing arrangements. The total notional amount of the interest rate swap was $25 million as of June 30, 2023. The interest rate swap agreement expires October 1, 2027. As a result of this agreement, every month we pay fixed interest at 4.455% in exchange for interest received at Term SOFR, and the fixed interest rate per annum on the first $25 million of notional value of the Term Loans will be 10.205% through its maturity. The interest rate swap agreement requires the Company to make deposits of cash collateral, which may increase or be refunded commensurate with fluctuations in current and forecasted interest rates. We have the contractual right to reclaim this cash collateral receivable.

The interest rate swap has been designated as a cash flow hedge. Consequently, changes in the fair value of the interest rate swap are recorded in accumulated other comprehensive loss ("AOCL") within stockholders' equity on the condensed consolidated balance sheets. The unrealized (losses) gains on the interest rate swap associated with the interest payments on the Term Loans that are still forecasted to occur are included in AOCL. These (losses) gains will be reclassified into interest expense on the condensed consolidated statements of operations over the life of the swap agreement as the hedged interest payments occur. Upon termination of the derivative instrument or a change in the hedged item, any remaining fair value recorded on the condensed consolidated balance sheets will be recorded as interest expense consistent with the cash flows associated with the underlying hedged item. Cash flows associated with the interest rate swap are included in cash flows from operating activities on the condensed consolidated statements of cash flows.

The net fair value of designated hedge derivatives subject to master netting arrangements reported on the condensed consolidated balance sheets was as follows:

| | Asset (Liability) | | | | | |
|---|---|---|---|---|---|---|
| *(In thousands)* | Gross Recognized Amount | Gross Offset Amount | Net Amount Presented | Cash Collateral Receivable | Net Amount Reported | Balance Sheet Location |
| June 30, 2023 | | | | | | |
| Interest rate swap | $ (160) | $ — | $ (160) | $ 545 | $ 385 | Other assets, noncurrent |
| September 30, 2022 | | | | | | |
| — | $ — | $ — | $ — | $ — | $ — | — |

The pretax amounts recognized in AOCL on the interest rate swap were as follows:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| *(In thousands)* | 2023 | 2022 | 2023 | 2022 |
| Beginning unrealized net gain (loss) in AOCL | $ — | $ — | $ — | $ — |
| Net gain (loss) recognized in other comprehensive income (loss) | 607 | — | (141) | — |
| Net (gain) loss reclassified into interest expense | (39) | — | (19) | — |
| Ending unrealized net gain (loss) in AOCL | $ 568 | $ — | $ (160) | $ — |

**8. Stock-based Compensation Plans**

The Company has stock-based compensation plans approved by its shareholders under which it grants stock options, restricted stock awards, restricted stock units and deferred stock units to officers, directors and key employees. Stock-based compensation expense was reported as follows in the condensed consolidated statements of operations:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| *(In thousands)* | 2023 | 2022 | 2023 | 2022 |
| Product costs | $ 63 | $ 62 | $ 202 | $ 170 |
| Research and development | 353 | 355 | 1,056 | 1,086 |
| Selling, general and administrative | 1,499 | 1,382 | 4,404 | 3,942 |
| Total | $ 1,915 | $ 1,799 | $ 5,662 | $ 5,198 |

As of June 30, 2023, unrecognized compensation costs related to non-vested awards totaled approximately $12.5 million, which is expected to be recognized over a weighted average period of approximately 2.3 years.

*Stock Option Awards*

The Company awards stock options to officers, directors and key employees and uses the Black-Scholes option pricing model to determine the fair value of stock options as of the date of each grant. Stock option grant activity was as follows:

| | Nine Months Ended June 30, | |
|---|---|---|
| | 2023 | 2022 |
| Stock option grant activity: | | |
| Stock options granted | 305,000 | 312,000 |
| Weighted average grant date fair value | $ 15.03 | $ 16.11 |
| Weighted average exercise price | $ 34.79 | $ 42.78 |

*Restricted Stock Awards*

During the nine months ended June 30, 2023 and 2022, the Company awarded 102,000 and 90,000 restricted stock shares, respectively, to certain key employees and officers with a weighted average grant date fair value per share of $35.84 and $43.02, respectively. Restricted Stock is valued based on the market value of the shares as of the date of grant.

*Restricted Stock Unit Awards*

During each of the nine months ended June 30, 2023 and 2022, the Company awarded 16,000 and 14,000 restricted stock units ("RSUs"), respectively, to directors and to key employees in foreign jurisdictions with a weighted average grant date fair value per unit of $31.72 and $42.79, respectively. RSUs are valued based on the market value of the shares as of the date of grant.

*Employee Stock Purchase Plan*

Our U.S. employees are eligible to participate in the amended 1999 Employee Stock Purchase Plan ("ESPP") approved by our shareholders. During the nine months ended June 30, 2023 and 2022, 23,000 and 10,000 shares, respectively, were issued under the ESPP.

**9. Net Income (Loss) Per Share Data**

Basic net income (loss) per common share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common and common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from dilutive common stock options and non-vested stock relating to restricted stock awards and restricted stock units. The calculation of diluted income (loss) per share excluded 0.1 million and less than 0.1 million in weighted-average shares for the three months ended June 30, 2023 and 2022, respectively, and 0.1 million in weighted-average shares for each of the nine months ended June 30, 2023 and 2022, as their effect was anti-dilutive.

The following table presents the denominator for the computation of diluted weighted average shares outstanding:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| *(In thousands)* | 2023 | 2022 | 2023 | 2022 |
| Basic weighted average shares outstanding | 14,050 | 13,929 | 14,020 | 13,907 |
| Dilutive effect of outstanding stock options, non-vested restricted stock, and non-vested restricted stock units | 22 | — | — | — |
| Diluted weighted average shares outstanding | 14,072 | 13,929 | 14,020 | 13,907 |

**10. Income Taxes**

For interim income tax reporting, the Company estimates its full-year effective tax rate and applies it to fiscal year-to-date pretax income (loss), excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company reported an income tax expense of $(13.3) million and income tax benefit of $1.5 million for the three months ended June 30, 2023 and 2022, respectively. For the nine months ended June 30, 2023 and 2022, the Company reported income tax expense of $(13.5) million and income tax benefit of $3.2 million, respectively.

- In the fourth quarter of fiscal 2022, we established a full valuation allowance against U.S. net deferred tax assets as of September 30, 2022. As a result, in fiscal 2023, we are no longer recording a tax benefit associated with U.S. pretax losses and incremental deferred tax assets.
- Recurring items cause our effective tax rate to differ from the U.S. federal statutory rate of 21%, including foreign-derived intangible income ("FDII") deductions in the U.S., U.S. federal and Irish R&D credits, Irish and U.S. state tax rates, and excess tax benefits associated with stock-based compensation.
- Beginning in our fiscal 2023, certain R&D costs are required to be capitalized and amortized over a five-year period under the Tax Cuts and Jobs Act enacted in December 2017. This change will impact the expected U.S. federal and state income tax expense and cash taxes to be paid for our fiscal 2023.

A valuation allowance is required to be recognized against deferred tax assets if, based on the available evidence, it is more likely than not (defined as a likelihood of more than 50%) that all or a portion of such assets will not be realized. The relevant guidance weighs available evidence such as historical cumulative taxable losses more heavily than future profitability. The valuation allowance has no impact on the availability of U.S. net deferred tax assets to offset future tax liabilities. Each reporting period, we evaluate the realizability of our net deferred tax assets and perform an assessment of both positive and negative evidence. Based on our evaluation of all available positive and negative evidence, and by placing greater weight on the objective negative evidence associated with our three-year cumulative U.S. pre-tax loss adjusted for permanent adjustments, we determined, as of June 30, 2023 and September 30, 2022, that it is more likely than not that our net U.S. deferred tax assets will not be realized. Accordingly, a full valuation allowance is recorded against our net U.S. deferred tax assets as of June 30, 2023 and September 30, 2022. Due to significant estimates used to establish the valuation allowance and the potential for changes in facts and circumstances, it is reasonably possible that we will be required to record additional adjustments to the valuation allowance in future reporting periods that could have a material effect on our results of operations.

Discrete tax (expense) benefit related to stock-based compensation awards vested, expired, canceled and exercised was $0.1 million or less for each of the three and nine months ended June 30, 2023 and 2022. The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate was $3.1 million and $2.5 million as of June 30, 2023 and September 30, 2022, respectively. Interest and penalties related to unrecognized tax benefits are recorded in the income tax (expense) benefit.

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions, as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. The Internal Revenue Service commenced an examination of the Company's fiscal 2019 U.S. federal tax return in fiscal 2022; the examination has not been completed. U.S. federal income tax returns for years prior to fiscal 2019 are no longer subject to examination by federal tax authorities. For tax returns for U.S. state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2012. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2018. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical, Ltd.; NorMedix, Inc.; and Vetex for periods prior to the respective acquisition dates, pursuant to the terms of the related share purchase agreements. There were no undistributed earnings in foreign subsidiaries as of June 30, 2023 and September 30, 2022.

**11. Commitments and Contingencies**

*Clinical Trials*. The Company has engaged clinical trial clinical research organization ("CRO") consultants to assist with the administration of its ongoing clinical trials. The Company executed separate contracts with two CROs for services in connection with the TRANSCEND pivotal clinical trial for the *SurVeil* DCB, including pass-through expenses paid by the CROs, of up to approximately $30 million in the aggregate. As of June 30, 2023, an estimated $2 million remains to be paid on one of these contracts, which may vary depending on actual pass-through expenses incurred to execute the trial. The Company estimates that the total cost of the TRANSCEND clinical trial will be in the range of $37 million to $40 million from inception to completion. In the event the Company were to terminate any trial, it may incur certain financial penalties which would become payable to the CRO for costs to wind down the terminated trial.

*Asset Acquisitions*. In fiscal 2018, the Company acquired certain intellectual property assets of Embolitech, LLC (the "Embolitech Transaction"). As part of the Embolitech Transaction, the Company paid the sellers $5.0 million in fiscal 2018, $1.0 million in fiscal 2020, $1.0 million in fiscal 2021, $0.5 million in fiscal 2022, and $1.0 million in the second quarter of fiscal 2023. The Company is obligated to pay an additional installment of $1.0 million in fiscal 2024, which may be accelerated upon the occurrence of certain sales and regulatory milestones. An additional $1.0 million payment is contingent upon the achievement of certain regulatory milestones within a contingency period ending in 2033.

*Vetex Acquisition*. In fiscal 2021, Surmodics acquired all of the outstanding shares of Vetex with an upfront cash payment of $39.9 million. The Company is obligated to pay additional installments totaling $3.5 million in fiscal 2024 through fiscal 2027. These payments may be accelerated upon the occurrence of certain product development and regulatory milestones. An additional $3.5 million in payments is contingent upon the achievement of certain product development and regulatory milestones within a contingency period ending in fiscal 2027.

**12. Restructuring**

In the second quarter of fiscal 2023, we initiated a spending reduction plan intended to preserve capital and more closely align our capital allocation priorities with our strategic objectives, which included a workforce restructuring in our Medical Device segment. As a result, for the nine months ended June 30, 2023, we recorded $1.3 million in severance and related charges in restructuring expense on our condensed consolidated statements of operations, which represented the total estimated expense as of June 30, 2023 expected to be incurred associated with the workforce restructuring. Restructuring expense accruals included in accrued other liabilities on the condensed consolidated balance sheets were as follows:

| ***(In thousands)*** | | |
|---|---|---|
| Restructuring expense accruals as of September 30, 2022 | $ | — |
| Restructuring expense | | 1,282 |
| Payments | | (1,259) |
| Other adjustments | | — |
| Currency translation | | — |
| Restructuring expense accruals as of June 30, 2023 | $ | 23 |

Restructuring expense accruals as of June 30, 2023 are expected to be paid during the fourth quarter of fiscal 2023.

**13. Segment Information**

Segment revenue, operating income (loss), and depreciation and amortization were as follows:

| *(In thousands)* | Three Months Ended June 30, 2023 | Three Months Ended June 30, 2022 | Nine Months Ended June 30, 2023 | Nine Months Ended June 30, 2022 |
|---|---|---|---|---|
| **Revenue:** | | | | |
| Medical Device | $ 46,014 | $ 17,528 | $ 84,739 | $ 52,889 |
| In Vitro Diagnostics | 6,469 | 7,326 | 19,875 | 21,074 |
| Total revenue | $ 52,483 | $ 24,854 | $ 104,614 | $ 73,963 |
| | | | | |
| **Operating income (loss):** | | | | |
| Medical Device | $ 21,777 | $ (7,308) | $ 7,483 | $ (16,712) |
| In Vitro Diagnostics | 2,866 | 3,387 | 9,450 | 10,262 |
| Total segment operating income (loss) | 24,643 | (3,921) | 16,933 | (6,450) |
| Corporate | (3,231) | (3,222) | (9,333) | (9,034) |
| Total operating income (loss) | $ 21,412 | $ (7,143) | $ 7,600 | $ (15,484) |
| | | | | |
| **Depreciation and amortization:** | | | | |
| Medical Device | $ 1,997 | $ 2,020 | $ 5,883 | $ 6,347 |
| In Vitro Diagnostics | 78 | 88 | 230 | 260 |
| Corporate | 76 | 98 | 252 | 295 |
| Total depreciation and amortization | $ 2,151 | $ 2,206 | $ 6,365 | $ 6,902 |

The Corporate category includes expenses that are not fully allocated to the Medical Device and In Vitro Diagnostics segments. These Corporate costs are related to administrative corporate functions, such as executive management, corporate accounting, information technology, legal, human resources and Board of Directors. Corporate may also include expenses, such as acquisition-related costs and litigation, which are not specific to a segment and thus not allocated to the reportable segments.

Asset information by segment is not presented because the Company does not provide its chief operating decision maker assets by segment, as the data is not readily available.

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

The following discussion and analysis provides information management believes is useful in understanding the operating results, cash flows and financial condition of Surmodics. The discussion should be read in conjunction with both the unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations, each included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022. This discussion contains various "Forward-Looking Statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We refer readers to the statement entitled "Forward-Looking Statements" located at the end of this Item 2.

**Overview**

Surmodics, Inc. (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms) is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic ("IVD") immunoassay tests and microarrays. Surmodics develops and commercializes highly differentiated vascular intervention medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The Company's mission is to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

**Vascular Intervention Medical Device Platforms**

Within our Medical Device segment, we develop and manufacture our own proprietary vascular intervention medical device products, which leverage our expertise in performance coating technologies, product design and engineering capabilities. We believe our strategy of developing our own medical device products has increased, and will continue to increase, our relevance in the medical device industry. This strategy is key to our future growth and profitability, providing us with the opportunity to capture more revenue and operating margin with vascular intervention device products than we would by licensing our device-enabling technologies.

Highlighted below are select medical device products within our development pipeline that are a focus for development and commercialization efforts. For both our thrombectomy and radial access platforms, we are pursuing commercialization via a direct sales strategy leveraging a small team of experienced sales professionals and clinical specialists. Beginning in fiscal 2022, we began to see modest, but meaningful and growing revenue associated with the adoption, utilization and sales of our Pounce™ and Sublime™ platform products.

*Pounce™ Thrombectomy Platform*

We have successfully developed, internally and through acquisitions, multiple U.S. Food and Drug Administration ("FDA" or the "Agency") 510(k)-cleared mechanical thrombectomy devices for the non-surgical removal of thrombi and emboli (clots) from the peripheral vasculature (legs). In addition to FDA clearance, our *Pounce* Venous Thrombectomy System has received the Conformité Européenne Mark ("CE Mark") approval prerequisite for commercialization in the European Union ("E.U."). We believe that the ease of use, intuitive design and efficient performance of our thrombectomy products make these devices viable first-line treatment options for interventionalists. These devices include:

- ***Pounce* Arterial Thrombectomy System** for removal of clots from arteries in the legs associated with peripheral arterial disease ("PAD"). Commercial sales began in the first quarter of fiscal 2022.

  In the third quarter of fiscal 2023, the low-profile (LP) model of the *Pounce* Arterial Thrombectomy System received FDA 510(k) regulatory clearance, which will allow for clot removal in below-the-knee peripheral arteries (2 mm to 4 mm in diameter), expanding the addressable market for the *Pounce* platform. Limited market evaluations are targeted to begin in the first quarter of fiscal 2024.

- ***Pounce* Venous Thrombectomy System** for removal of clots from veins in the legs generally associated with venous thromboembolism ("VTE"). Limited market evaluations began in fiscal 2023 and are expected to continue in fiscal 2023 to obtain physician feedback across a variety of cases and clinical conditions.

*Sublime Radial Access Platform*

We have successfully developed and secured FDA 510(k) regulatory clearance for a suite of devices that enable vascular intervention via radial (wrist) access for which commercial sales began in the first quarter of fiscal 2022. These devices include:

- ***Sublime* guide sheath** to provide the conduit for peripheral intervention with an access point at the wrist that enables treatment all the way to the pedal loop of the foot;
- ***Sublime* .014 RX PTA dilatation catheter** for treatment of lesions in arteries below the knee all the way to the patient's foot and around the pedal loop; and
- ***Sublime* .018 RX PTA dilatation catheter** for treatment of lesions in arteries above and below the knee.
- ***Sublime* microcatheter**, peripheral crossing catheters with multiple configurations (compatible with .014, .018 and .035 guidewires), for access to arterial lesions above and below the knee using radial, femoral, or alternate access site approaches. Limited market evaluations of the *Sublime* microcatheter began in the third quarter of fiscal 2023 and are expected to continue in fiscal 2023.

*Drug-coated Balloon Platform*

Surmodics' drug-coated balloons ("DCBs") are designed for vascular interventions to treat PAD, a condition that causes a narrowing of the blood vessels supplying the extremities.

- **SurVeil™ DCB** is a paclitaxel-coated DCB to treat PAD in the upper leg (superficial femoral artery). In fiscal 2018, we entered into an agreement (the "Abbott Agreement") with Abbott Vascular, Inc. ("Abbott") that provides Abbott with exclusive worldwide commercialization rights to the *SurVeil* DCB product. Our *SurVeil* DCB utilizes a proprietary paclitaxel drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity.

  The *SurVeil* DCB has the necessary regulatory approval for commercialization in the E.U., and timing of commercialization in the E.U. is at the discretion of our exclusive distribution partner, Abbott. In fiscal 2021, the TRANSCEND pivotal clinical trial of our *SurVeil* DCB met both the primary safety and primary efficacy endpoints and was found to be non-inferior to the control device in those endpoints.

  In June 2023, the *SurVeil* DCB received FDA premarket approval ("PMA") and may now be marketed and sold in the U.S. by our exclusive distribution partner, Abbott. Under the Abbott Agreement, Abbott has the right to purchase commercial units from us, and we will realize revenue from product sales to Abbott at an agreed-upon transfer price, as well as a share of net profits resulting from third-party product sales by Abbott. Timing of commercialization in the U.S. is at the discretion of Abbott and is targeted for fiscal 2024.
- **Sundance™ DCB** is a sirolimus-coated DCB used for the treatment of below-the-knee PAD. We completed six-month patient follow-up visits in the fourth quarter of fiscal 2021 for the SWING first-in-human, 35-patient clinical study of our *Sundance* DCB. In fiscal 2022, we finalized the clinical report for the SWING trial, which demonstrated promising early safety data and performance insights. We plan to evaluate our strategy for further clinical investment in the *Sundance* DCB based on the experience we have gained from the PMA application process for the *SurVeil* DCB.

For more information regarding our vascular intervention medical devices, see Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

**Results of Operations**

***Three and Nine Months Ended June 30, 2023 and 2022***

*Revenue.* Revenue in the third quarter of fiscal 2023 was $52.4 million, a $27.6 million or 111% increase compared to the prior-year quarter. Revenue in the first nine months of fiscal 2023 was $104.6 million, a $30.7 million or 41% increase compared to the same prior-year period. The following is a summary of revenue streams within each reportable segment.

| | Three Months Ended June 30, | | | | Nine Months Ended June 30, | | | |
|---|---|---|---|---|---|---|---|---|
| *(Dollars in thousands)* | 2023 | 2022 | Increase/(Decrease) | | 2023 | 2022 | Increase/(Decrease) | |
| **Medical Device** | | | | | | | | |
| Product sales | $ 9,299 | $ 6,741 | $ 2,558 | 38 % | $ 25,593 | $ 19,970 | $ 5,623 | 28 % |
| Royalties | 8,220 | 7,771 | 449 | 6 % | 23,702 | 23,015 | 687 | 3 % |
| License fees | 25,933 | 1,024 | 24,909 | 2,433 % | 28,645 | 3,723 | 24,922 | 669 % |
| R&D and other | 2,562 | 1,992 | 570 | 29 % | 6,799 | 6,181 | 618 | 10 % |
| **Medical Device Revenue** | **46,014** | **17,528** | **28,486** | **163 %** | **84,739** | **52,889** | **31,850** | **60 %** |
| **In Vitro Diagnostics** | | | | | | | | |
| Product sales | 6,368 | 7,178 | (810) | (11) % | 19,658 | 20,257 | (599) | (3) % |
| R&D and other | 101 | 148 | (47) | (32) % | 217 | 817 | (600) | (73) % |
| **In Vitro Diagnostics Revenue** | **6,469** | **7,326** | **(857)** | (12) % | **19,875** | **21,074** | **(1,199)** | (6) % |
| **Total Revenue** | **$ 52,483** | **$ 24,854** | **$ 27,629** | **111 %** | **$ 104,614** | **$ 73,963** | **$ 30,651** | **41 %** |

*Medical Device.* Revenue in our Medical Device segment was $46.0 million in the third quarter of fiscal 2023, a 163% increase from $17.5 million in the prior-year quarter. Revenue in our Medical Device segment was $84.7 million in the first nine months of fiscal 2023, a 60% increase from $52.9 million in the same prior-year period.

- Medical Device product sales increased 37.9% to $9.3 million in the third quarter of fiscal 2023, compared to $6.7 million in the prior-year quarter. For the first nine months of fiscal 2023, Medical Device product sales increased 28.2% to $25.6 million, compared to $20.0 million in the same prior-year period. Product sales growth year-over-year in the third quarter and first nine months of fiscal 2023 was primarily driven by increased sales of our *Pounce* thrombectomy and *Sublime* radial access device products, which were commercialized in fiscal 2022. Increased sales of performance coating reagent products and increased sales of contract-manufactured balloon catheters also contributed to the growth in product sales year-over-year in the third quarter and first nine months of fiscal 2023.
- Medical Device performance coating royalties revenue increased 5.8% to $8.2 million in the third quarter of fiscal 2023, compared to $7.8 million in the prior-year quarter. For the first nine months of fiscal 2023, Medical Device performance coating royalties revenue increased 3.0% to $23.7 million, compared to $23.0 million in the same prior-year period. For the third quarter and first nine months of fiscal 2023, year-over-year growth was primarily driven by customers utilizing our Serene™ coating. In addition, performance coating royalties revenue for the first nine months of fiscal 2023 was impacted by macroeconomic factors to a lesser degree relative to the same prior-year period. Macroeconomic factors include pressure on procedure volumes from hospital capacity constraints and customer supply chain disruptions, as well as customer devices maturing through their product life cycle.
- License fee revenue from the Abbott Agreement for our *SurVeil* DCB was $25.9 million and $1.0 million in the third quarter of fiscal 2023 and 2022, respectively, and $28.5 and $3.6 million in the first nine months of fiscal 2023 and 2022, respectively. In June 2023, we received a $27.0 million milestone payment from Abbott upon FDA premarket approval of the *SurVeil* DCB, of which $24.6 million was recognized as revenue in the third quarter and first nine months of fiscal 2023.
- Medical Device research and development ("R&D") and other revenue increased $0.6 million, or 29%, in the third quarter of fiscal 2023 and increased $0.6 million, or 10%, in the first nine months of fiscal 2023, compared to the same respective prior-year periods, driven by increased volume of performance coating services.

*In Vitro Diagnostics.* Revenue in our In Vitro Diagnostics ("IVD") segment was $6.5 million in the third quarter of fiscal 2023, a 12% decrease from $7.3 million in the prior-year quarter. Revenue in our In Vitro Diagnostics segment was $19.9 million in the first nine months of fiscal 2023, a 6% decrease from $21.1 million in the same prior-year period.

- IVD product sales declined 11% to $6.4 million in the third quarter of fiscal 2023, compared to $7.2 million in the prior-year quarter. For the first nine months of fiscal 2023, IVD products sales declined 3% to $19.7 million, compared to $20.3 million in the same prior-year period. For both the third quarter and first nine months of fiscal 2023, the year-over-year decline in sales was driven primarily by active management of inventory levels by certain customers. For the first nine months of fiscal 2023, the year-over-year decline in sales was partly offset by growth in sales of our microarray slide/surface products.

- IVD R&D and other revenue was $0.1 million for both the third quarter of fiscal 2023 and 2022. For the first nine months of fiscal 2023, IVD R&D and other revenue declined to $0.2 million, compared to $0.8 million in the same prior-year period, due to the completion of a customer development program.

*Operating Costs and Expenses.* Product sales, product costs, product gross profit, product gross margin, and operating costs were as follows:

| | Three Months Ended June 30, | | | Nine Months Ended June 30, | | |
|---|---|---|---|---|---|---|
| *(Dollars in thousands)* | 2023 | 2022 | Increase/(Decrease) | 2023 | 2022 | Increase/(Decrease) |
| Product sales | $ 15,667 | $ 13,919 | $ 1,748 13 % | $ 45,251 | $ 40,227 | $ 5,024 12 % |
| Product costs | 6,921 | 5,141 | 1,780 35 % | 17,926 | 14,745 | 3,181 22 % |
| Product gross profit (1) | 8,746 | 8,778 | (32) — % | 27,325 | 25,482 | 1,843 7 % |
| % Product gross margin (2) | 55.8 % | 63.1 % | (7.3) ppt | 60.4 % | 63.3 % | (2.9) ppt |
| R&D expense | 11,232 | 12,975 | (1,743) (13) % | 36,899 | 38,350 | (1,451) (4) % |
| % Total revenue | 21 % | 52 % | | 35 % | 52 % | |
| SG&A expense | 12,874 | 12,854 | 20 — % | 39,077 | 33,159 | 5,918 18 % |
| % Total revenue | 25 % | 52 % | | 37 % | 45 % | |
| Acquired intangible asset amortization | 879 | 1,024 | (145) (14) % | 2,659 | 3,184 | (525) (16) % |
| Restructuring expense | — | — | — | 1,282 | — | 1,282 |
| Contingent consideration (gain) expense | (835) | 3 | (838) | (829) | 9 | (838) |

(1) Product gross profit is defined as product sales less related product costs.

(2) Product gross margin is defined as product gross profit as a percentage of product sales.

*Product gross margins.* Product gross margins were 55.8% and 63.1% in the third quarter of fiscal 2023 and 2022, respectively, and 60.4% and 63.3% in the first nine months of fiscal 2023 and 2022, respectively. In the third quarter and first nine months of fiscal 2023, the decline in product gross margin was primarily driven by the adverse mix impact from increased device product sales, which have lower product gross margins due to low production volumes. Product gross margins may continue to be impacted by the shift in revenue mix towards sales of medical devices at relatively lower margins, particularly during the scale-up phase following initial commercialization.

*R&D expense.* R&D expense declined 13% in the third quarter of fiscal 2023, or $1.7 million, compared to the prior-year quarter. For the first nine months of fiscal 2023, R&D expense declined 4%, or $1.5 million, compared to the same prior-year period. R&D expense as a percentage of revenue was 21% and 52% in the third quarter of fiscal 2023 and 2022, respectively, and 35% and 52% in the first nine months of fiscal 2023 and 2022, respectively. The decline in R&D expense as a percentage of revenue reflects the impact of higher revenue in the third quarter and first nine months of fiscal 2023, principally from the $24.6 million in license fee revenue recognized in the period upon receipt of the $27.0 million *SurVeil* DCB PMA milestone payment under the Abbott Agreement. In the second quarter of fiscal 2023, we initiated a spending reduction plan, including a workforce restructuring, to refocus our investments in product development to prioritize progress primarily on our near-term growth opportunities, which resulted in a year-over-year decrease in R&D expense in the third quarter and first nine months of fiscal 2023. For the third quarter and first nine months of fiscal 2023, R&D expense reflects continued investment in medical device product development, including in our *Pounce* thrombectomy and *Sublime* radial access product platforms and costs associated with our *SurVeil* DCB.

*Selling, general and administrative ("SG&A") expense.* SG&A expense was flat in the third quarter of fiscal 2023, compared to the prior-year quarter. For the first nine months of fiscal 2023, SG&A expense increased 17.8%, or $5.9 million, compared to the same prior-year period. SG&A expense as a percentage of revenue was 25% and 52% in the third quarter of fiscal 2023 and 2022, respectively, and 37% and 45% in the first nine months of fiscal 2023 and 2022, respectively. The decline in SG&A expense as a percentage of revenue reflects the impact of higher revenue in the third quarter and first nine months of fiscal 2023, principally from the $24.6 million in license fee revenue recognized in the period upon receipt of the $27.0 million *SurVeil* DCB PMA milestone payment under the Abbott Agreement. For the first nine months of fiscal 2023, the increase in SG&A expense was primarily driven by a year-over-year increase in headcount. Throughout fiscal 2022, we invested in a medical device direct salesforce to support the fiscal 2022 commercialization of our *Pounce* and *Sublime* product platforms. We expect SG&A expense for full-year fiscal 2023 to increase between $5.5 million and $6.5 million, compared to fiscal 2022, primarily due to higher average SG&A headcount levels in fiscal 2023 than in fiscal 2022.

*Acquired intangible asset amortization.* We have previously acquired certain intangible assets through business combinations, which are amortized over periods ranging from six to 14 years.

*Restructuring expense.* In the second quarter of fiscal 2023, we initiated a spending reduction plan intended to preserve capital and more closely align our capital allocation priorities with our strategic objectives, which included a workforce restructuring in our Medical Device segment. As a result, in the first nine months of fiscal 2023, we recorded $1.3 million in severance and related charges in restructuring expense, which represented the total estimated expense as of June 30, 2023 associated with the workforce restructuring.

*Contingent consideration (gain) expense.* In the third quarter and first nine months of fiscal 2023, we reported a $0.8 gain from the fair value adjustment of acquisition-related contingent consideration liabilities. Gain (expense) recognized is related to changes in the probability and timing of achieving certain contractual milestones, as well as accretion expense for the passage of time.

*Other expense.* Major classifications of other expense were as follows:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| ***(In thousands)*** | **2023** | **2022** | **2023** | **2022** |
| Interest expense, net | $ (884) | $ (145) | $ (2,594) | $ (410) |
| Foreign exchange (loss) gain | (61) | 85 | (261) | 120 |
| Investment income, net | 182 | 22 | 531 | 73 |
| Other expense | $ (763) | $ (38) | $ (2,324) | $ (217) |

Interest expense, net increased in the third quarter and first nine months of fiscal 2023, compared to the same respective prior-year periods, due to increased borrowing and higher interest rates. Refer to “Liquidity and Capital Resources” for further discussion of financing arrangements and expectations for fiscal 2023 interest expense. Foreign currency exchange (losses) gains result primarily from the impact of U.S. dollar to Euro exchange rate fluctuations on certain intercompany transactions and balances. Investment income, net increased in the third quarter and first nine months of fiscal 2023, compared to the same respective prior-year periods, due to higher interest rates.

*Income taxes*. We reported income tax expense of $(13.3) million and income tax benefit of $1.5 million in the third quarter of fiscal 2023 and 2022, respectively. For the first nine months of fiscal 2023 and 2022, we reported income tax expense of $(13.5) million and income tax benefit of $3.2 million, respectively. Our effective tax rate was 65% and 21% for the third quarter of fiscal 2023 and 2022, respectively, and 256% and 20% for the first nine months of fiscal 2023 and 2022, respectively.

- In the fourth quarter of fiscal 2022, we established a full valuation allowance against U.S. net deferred tax assets as of September 30, 2022. As a result, in fiscal 2023, we are no longer recording a tax benefit associated with U.S. pretax losses and incremental deferred tax assets. A valuation allowance is required to be recognized against deferred tax assets if, based on the available evidence, it is more likely than not (defined as a likelihood of more than 50%) that all or a portion of such assets will not be realized. The relevant guidance weighs available evidence such as historical cumulative taxable losses more heavily than future profitability. The valuation allowance has no impact on the availability of U.S. net deferred tax assets to offset future tax liabilities.
- Recurring items cause our effective tax rate to differ from the U.S. federal statutory rate of 21%, including foreign-derived intangible income (“FDII”) deductions in the U.S., U.S. federal and Irish R&D credits, Irish and U.S. state tax rates, and excess tax benefits associated with stock-based compensation.
- Beginning in our fiscal 2023, certain R&D costs are required to be capitalized and amortized over a five-year period under the Tax Cuts and Jobs Act enacted in December 2017. This change will impact the expected U.S. federal and state income tax expense and cash taxes to be paid for our fiscal 2023.

**Segment Operating Results**

Operating results for each of our reportable segments were as follows:

| | Three Months Ended June 30, | | | Nine Months Ended June 30, | | |
|---|---|---|---|---|---|---|
| *(In thousands)* | 2023 | 2022 | $ Change | 2023 | 2022 | $ Change |
| Operating income (loss): | | | | | | |
| Medical Device | $ 21,777 | $ (7,308) | $ 29,085 | $ 7,483 | $ (16,712) | $ 24,195 |
| In Vitro Diagnostics | 2,866 | 3,387 | (521) | 9,450 | 10,262 | (812) |
| Total segment operating income (loss) | 24,643 | (3,921) | 28,564 | 16,933 | (6,450) | 23,383 |
| Corporate | (3,231) | (3,222) | (9) | (9,333) | (9,034) | (299) |
| Total operating income (loss) | $ 21,412 | $ (7,143) | $ 28,555 | $ 7,600 | $ (15,484) | $ 23,084 |

*Medical Device*. Our Medical Device business reported operating income of $21.8 million in the third quarter of fiscal 2023, compared to an operating loss of $(7.3) million in the prior-year quarter, representing 47% and (42)% of revenue, respectively. For the first nine months of fiscal 2023, our Medical Device business reported operating income of $7.5 million, compared to an operating loss of $(16.7) million in the same prior-year period, representing 9% and (32)% of revenue, respectively.

- Medical Device royalties and license fee revenue increased $25.4 and $25.6 million year-over-year in the third quarter and first nine months of fiscal 2023, respectively. In June 2023, we received a $27.0 million milestone payment from Abbott upon FDA premarket approval of the *SurVeil* DCB, of which $24.6 million was recognized as license fee revenue in the third quarter and first nine months of fiscal 2023. Medical Device performance coatings royalties revenue grew 5.8% and 3.0% year-over-year in the third quarter and first nine months of fiscal 2023, respectively, driven primarily by customers utilizing our Serene™ coating.
- Medical Device operating expenses, excluding product costs, decreased $2.7 million and $4.3 million year-over-year in the third quarter and first nine months of fiscal 2023, respectively. The third quarter and first nine months of fiscal 2023 included a $0.8 million gain from the fair value adjustment of acquisition-related contingent consideration. The first nine months of fiscal 2023 included $1.3 million in severance-related restructuring expense as the result of a workforce restructuring.

  R&D expenditures in our Medical Device segment declined year-over-year in the third quarter and first nine months of fiscal 2023. During the second quarter of fiscal 2023, we initiated a spending reduction plan, including a workforce restructuring, to refocus our investments in product development to prioritize progress primarily on our near-term growth opportunities. For the third quarter and first nine months of fiscal 2023, R&D expense reflects continued investment in medical device product development, including in our *Pounce* thrombectomy and *Sublime* radial access product platforms and costs associated with our *SurVeil* DCB.

  SG&A expense in our Medical Device business declined modestly year-over-year in the third quarter of fiscal 2023, and SG&A expense increased year-over-year in the first nine months of fiscal 2023 primarily related to increased headcount. Throughout fiscal 2022, we invested in a medical device direct salesforce to support the fiscal 2022 commercialization of our *Pounce* and *Sublime* product platforms.
- Medical Device product gross profit increased $0.4 million and $2.3 million year-over-year in the third quarter and first nine months of fiscal 2023, respectively, driven by growth in sales of performance coating reagents. Product gross margins were 49.0% and 61.3% in the third quarter of fiscal 2023 and 2022, respectively, and 55.4% and 59.5% in the first nine months of fiscal 2023 and 2022, respectively. In the third quarter and first nine months of fiscal 2023, the decline in product gross margin was primarily driven by the adverse mix impact from increased device product sales, which have lower product gross margins due to low production volumes during the scale-up phase following initial commercialization.

*In Vitro Diagnostics*. Our In Vitro Diagnostics business reported operating income of $2.9 million and $3.4 million in the third quarter of fiscal 2023 and 2022, respectively, representing 44% and 46% of revenue, respectively. For the first nine months of fiscal 2023 and 2022, our In Vitro Diagnostics business reported operating income of $9.5 million and $10.3 million, respectively, representing 48% and 49% of revenue, respectively.

- IVD product gross profit declined $0.5 million year-over-year in both the third quarter and first nine months of fiscal 2023. IVD product gross margins were 65.9% and 64.8% in the third quarter fiscal 2023 and 2022, respectively, and 66.8% and 67.1% in the first nine months of fiscal 2023 and 2022, respectively. The year-over-year increase in IVD product gross margin in the third quarter of fiscal 2023 was driven primarily by the favorable mix impact from the decline in sales of relatively lower margin distributed antigen products, partly offset by higher absorption of fixed costs. In the first nine months of fiscal 2023, the year-over-year decline in IVD product gross margin was driven primarily by higher absorption of fixed costs, partly offset by the favorable mix impact from the decline in antigens product sales.

- IVD R&D and other revenue was flat year-over-year in the third quarter of fiscal 2023 and declined $0.6 million year-over-year in the first nine months of fiscal 2023 related to the completion of a customer development program.

*Corporate*. The Corporate category includes expenses for administrative corporate functions, such as executive management, corporate accounting, information technology, legal, human resources and Board of Directors related fees and expenses, which we do not fully allocate to the Medical Device and IVD segments. Corporate also includes expenses, such as acquisition-related costs and litigation, which are not specific to a segment and thus not allocated to our reportable segments. The unallocated Corporate expense operating loss was $(3.2) million in both the third quarter of fiscal 2023 and 2022 and $(9.3) million and $(9.0) million in the first nine months of fiscal 2023 and 2022, respectively.

**Cash Flow Operating Results**

The following is a summary of cash flow results:

| | Nine Months Ended June 30, | |
|---|---|---|
| *(In thousands)* | 2023 | 2022 |
| Cash provided by (used in): | | |
| Operating activities | $ 9,264 | $ (14,723) |
| Investing activities | (2,170) | 4,802 |
| Financing activities | 17,987 | (673) |
| Effect of exchange rates on changes in cash and cash equivalents | 500 | (485) |
| Net change in cash and cash equivalents | $ 25,581 | $ (11,079) |

*Operating Activities*. Cash provided by operating activities was $9.3 million in the first nine months of fiscal 2023, compared to cash used of $(14.7) million in the same prior-year period. Net loss was $(8.2) million in in the first nine months of fiscal 2023, compared to $(12.5) million in the same prior-year period. Net changes in operating assets and liabilities increased cash flows from operating activities by $5.4 million in the first nine months of fiscal 2023 and reduced cash flows from operating activities by $(11.9) million in the same prior-year period. Significant changes in operating assets and liabilities affecting cash flows during these periods included:

- Cash used in deferred revenue was $(1.4) million in the first nine months of fiscal 2023, compared to cash used of $(3.5) million in the same prior-year period. The decrease in cash used was the result of the receipt of the $27.0 million *SurVeil* DCB PMA milestone payment under the Abbott Agreement, of which $2.4 million was recorded in deferred revenue on the condensed consolidated balance sheet as of June 30, 2023.
- Cash used in accrued liabilities was $(2.5) million in the first nine months of fiscal 2023, compared to cash used of $(1.0) million in the same prior-year period, primarily due to routine fluctuations in the timing of compensation and expense accruals.
- In addition, income taxes affected the change in operating assets and liabilities. In the first nine months of fiscal 2023, primarily as the result of the $27.0 million PMA milestone payment received in the period, the change in operating assets and liabilities included cash provided by income taxes of $15.6 million – driven primarily by a $12.0 million increase in income tax payable and the receipt of a $2.4 million tax refund under the net operating loss carryback provisions of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), during the first nine months of fiscal 2023. In the first nine months of fiscal 2022, the change in operating assets and liabilities included cash used in income taxes of $(0.7) million. Cash taxes paid was $0.3 million in the first nine months of fiscal 2023, compared to $0.4 million in the same prior-year period.

*Investing Activities*. Cash used in investing activities totaled $(2.2) million for the first nine months of fiscal 2023, compared to cash provided of $4.8 million in the same prior-year period. Capital expenditures for property and equipment totaled $2.2 million and $2.8 million in the first nine months of fiscal 2023 and 2022, respectively. In the prior-year period, maturities of available-for-sale investments were a source of cash of $7.6 million.

*Financing Activities*. Cash provided by financing activities totaled $18.0 million in the first nine months of fiscal 2023, compared to cash used of $(0.7) million in the same prior-year period. In the first quarter of fiscal 2023, the Company entered into a new, five-year secured credit agreement with MidCap Funding IV Trust, as agent, and MidCap Financial Trust, as term loan servicer and the lenders from time to time party thereto (together “MidCap”). The Company drew $25 million on the term loan and $5 million on the revolving credit facility at close. These proceeds were partially used to retire the Company’s existing revolving credit facility with Bridgewater Bank, of which $10 million was outstanding, as well as to pay a total of $1.0 million in debt issuance costs, including fees to MidCap and legal and other expenses directly associated with the financing transaction.

**Liquidity and Capital Resources**

As of June 30, 2023, working capital totaled $53.8 million, an increase of $28.3 million from September 30, 2022. We define working capital as current assets minus current liabilities. Cash and cash equivalents totaled $44.6 million as of June 30, 2023, an increase of $25.6 million from $19.0 million as of September 30, 2022.

The Company proactively manages its access to capital to support liquidity and continued growth. On October 14, 2022, Surmodics entered into a new, five-year secured credit agreement with MidCap, consisting of up to $100 million in term loans ($25 million of which is at the sole discretion of MidCap) and a $25 million revolving credit facility. At close, the Company drew $25 million on the term loan and $5 million on the revolving credit facility. These proceeds were partially used to retire the Company's then existing $25 million revolving credit facility with Bridgewater Bank, of which $10 million was outstanding. Upon closing in October 2022, the Company's cash balance increased by $19.5 million. In fiscal 2023, the Company expects total interest expense under the credit agreement with MidCap to be approximately $3.4 million.

- *Revolving Credit Facility*. Surmodics has access to a revolving credit facility, which provides for maximum availability of $25 million, subject to a borrowing base. As of June 30, 2023, the outstanding balance on the revolving credit facility was $5 million. As of June 30, 2023, additional, incremental availability on the revolving credit facility was approximately $10.8 million, based on borrowing base eligibility requirements consisting primarily of the Company's inventory and receivable balances. The revolving credit facility has an annual interest rate equal to 3.00% plus the greater of Term SOFR (as defined in the credit agreement) or 1.50%, and has a maturity date of October 1, 2027.
- *Term Loan*. Surmodics has access to additional draws on the term loan. As of June 30, 2023, the outstanding principal on the term loan was $25 million. Additional draws on the term loan may be made in increments of at least $10 million, up to a total of $50 million through December 31, 2024 subject to certain conditions, including having no less than $60 million of core net revenue on a rolling four-quarter basis. A second tranche of up to $25 million may be available through December 31, 2024 at MidCap's sole discretion. The credit agreement with MidCap calls for interest-only payments on the term loan over the first four years, which can be extended to five years if certain criteria are met. The Company has entered into an interest rate swap arrangement with Wells Fargo, whereby the initial $25 million borrowing on term loan's variable base rate was fixed at 10.205% per annum for the five-year loan term. The term loan has a maturity date of October 1, 2027.

As of June 30, 2023, the Company's shelf registration statement with the SEC allows the Company to offer potentially up to $200 million in debt securities, common stock, preferred stock, warrants, and other securities or any such combination of such securities in amounts, at prices, and on terms announced if and when the securities are ever offered. This shelf registration statement expires in May 2026.

In the second quarter of fiscal 2023, we initiated a spending reduction plan intended to preserve capital and more closely align our capital allocation priorities with our strategic objectives, which included a workforce restructuring that reduced our workforce by approximately 12%. As a result, we reported $1.3 million in restructuring expense for severance and related charges in the second quarter and first nine months of fiscal 2023, which represented the total estimated expense expected to be incurred associated with the workforce restructuring as of June 30, 2023.

In June 2023, the SurVeil DCB received FDA premarket approval and may now be marketed and sold in the U.S. by our exclusive distribution partner, Abbott. We received a $27.0 million milestone payment from Abbott in the third quarter of fiscal 2023, of which $24.6 million was recognized as revenue during the period. Under the Abbott Agreement, Abbott has the right to purchase commercial units from us, and we will realize revenue from product sales to Abbott at an agreed-upon transfer price, as well as a share of net profits resulting from third-party product sales by Abbott. Timing of commercialization in the U.S. is at the discretion of Abbott and is targeted for fiscal 2024.

In fiscal 2023, we anticipate a year-over-year increase in SG&A expenditures of between $5.5 million and $6.5 million. We expect that increasing SG&A expenditures in fiscal 2023 will exceed any corresponding increases in revenues, and therefore will reduce our cash flow from operations. We also anticipate R&D expenses will continue to be significant in fiscal 2023, primarily related to medical device product development, including continued investments in our *Pounce* and *Sublime* product platforms.

We believe that our existing cash and cash equivalents, which totaled $44.6 million as of June 30, 2023, together with cash flow from operations and our revolving credit facility and term loans, will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for fiscal 2023. There can be no assurance, however, that our business will continue to generate cash flows at historic levels.

Beyond fiscal 2023, our cash requirements will depend extensively on the timing of market introduction and extent of market acceptance of products in our medical device product portfolio, including the commercial launch of the *SurVeil* DCB by Abbott, our exclusive distribution partner for the product. Our long-term cash requirements also will be significantly impacted by the level of our investment in commercialization of our vascular intervention device products and whether we make future corporate transactions. We cannot accurately predict our long-term cash requirements at this time. We may seek additional sources of liquidity and capital resources, including through borrowing, debt or equity financing or corporate transactions to generate cash flow. There can be no assurance that such transactions will be available to us on favorable terms, if at all.

**Customer Concentrations**

We have agreements with a diverse base of customers and certain customers have multiple products using our technology. Abbott and Medtronic are our largest customers, comprising 11% and 13%, respectively, of our consolidated revenue for fiscal 2022. These same customers, Abbott and Medtronic, each comprised 32% and 10%, respectively, of our consolidated revenue for the nine months ended June 30, 2023. Revenue generated under our *SurVeil* DCB license agreement with Abbott represented 27% of total revenue for the nine months ended June 30, 2023. Apart from the *SurVeil* DCB license, Abbott has several separately licensed products which generate revenue for Surmodics, none of which represented more than 3% of total revenue for the nine months ended June 30, 2023. Medtronic has several separately licensed products that generate revenue for Surmodics, none of which represented more than 3% of our total revenue for the nine months ended June 30, 2023.

**Critical Accounting Policies and Significant Estimates**

Critical accounting policies are those policies that require the application of management's most challenging subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. For the nine months ended June 30, 2023, there were no significant changes in our critical accounting policies. For a detailed description of our other critical accounting policies and significant estimates, see Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

**Forward-looking Statements**

This Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 2, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, our strategies for growth, including our ability to sign new license agreements, conduct clinical evaluations, and bring new products to market; the expected initiation and duration of limited market evaluations for our products; the development of future products and their anticipated attributes; our initiations for product evaluation activities; the period over which deferred revenue related to the Abbott Agreement is expected to be recognized; revenue potential related to the potential commercial launch of the SurVeil DCB; our plans to evaluate our strategy for further clinical investment in the Sundance DCB; future revenue growth, our longer-term valuation-creation strategy, and our future potential; information about our product pipeline; future gross margins and operating expenses; the potential impact of a shift in revenue mix towards sales of medical devices; estimated future amortization expense; expectations regarding operating expenses and their impact on our cash flows; the estimated expense expected to be incurred associated with workforce restructurings; when restructuring accruals are expected to be paid; the period over which unrecognized compensation costs is expected to be recognized; research and development plans and expenses; the estimated amount remaining to be paid on contracts with clinical research organization consultants; the estimated total cost for the TRANSCEND clinical trial; anticipated cash requirements; the intended use of remaining proceeds of our borrowing under the MidCap Credit Agreement; future cash flows and sources of funding, and their ability together with existing cash, and cash equivalents, to provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for fiscal 2023; statements regarding cash requirements beyond fiscal 2023; expectations regarding capital available under our secured revolving credit facility and secured term loan facilities; expectations regarding the maturity of debt; future impacts of our interest rate swap transactions; the impact of potential lawsuits or claims; the potential impact of interest rate fluctuations on our results of operations and cash flows; the impact of potential change in raw material prices, sources of raw materials and our ability to manufacture raw materials ourselves; the potential impact on the Company of currency fluctuations; future income tax (expense) benefit; expected income tax expense and cash taxes to be paid; the likelihood that we will realize the benefits of our deferred tax assets; and the impact of the adoption of new accounting pronouncements. Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar terminology, generally identify forward-looking statements. Forward-looking statements may also represent challenging goals for us. These statements, which represent our expectations or beliefs concerning various future events, are based on current expectations that involve a number of risks and uncertainties that could cause actual results to differ materially from those of such forward-looking statements. We caution that undue reliance should not be placed on such forward-looking statements, which speak only as of the date made. Some

of the factors which could cause results to differ from those expressed in any forward-looking statement are set forth under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022 and in our Quarterly Report on Form 10-Q for the three months ended December 31, 2022. We disclaim any intent or obligation to update publicly these forward-looking statements, whether because of new information, future events or otherwise.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from our forward-looking statements, such factors include, among others:

1. ongoing operating losses, increased interest expense, and failure to generate cash flows from operations, which could impact expected expenditures and investments in growth initiatives;
2. our reliance on a small number of significant customers, including our largest customers, Abbott and Medtronic, which causes our financial results and stock price to be subject to factors affecting those significant customers and their products, the timing of market introduction of their or competing products, product safety or efficacy concerns and intellectual property litigation impacting such customers, which could adversely affect our growth strategy and the royalties revenue we derive;
3. clinical and regulatory developments relating to the evaluation of risks associated with paclitaxel-coated products, which developments may adversely impact our ability to complete our TRANSCEND clinical trial on any particular time frame, obtain marketing approval (or the timing of any such approval) for our *SurVeil* DCB and other paclitaxel-coated products, to treat peripheral artery disease in the femoral and/or popliteal arteries;
4. our ability to successfully develop, obtain and maintain regulatory approval for, commercialize, and manufacture at commercial volumes our *SurVeil* and other DCB products, including our reliance on clinical research organizations to manage the TRANSCEND clinical trial and uncertainty related to the impacts of any clinical research relative to drug-coated balloons and other catheter and balloon-based products;
5. general economic conditions that are beyond our control, such as the impact of recession, inflation, rising interest rates, customer mergers and acquisitions, business investment, changes in consumer confidence, and medical epidemics or pandemics such as the COVID-19 pandemic;
6. our ability to successfully and profitably commercialize our vascular intervention products, including our *Pounce* Venous Thrombectomy System, through our direct salesforce, or otherwise;
7. our ability to comply with the terms of our secured revolving credit facility and secured term loan facilities;
8. the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances or approvals, which may result in lost market opportunities, failure to bring new products to market or postpone or preclude product commercialization by licensees or ourselves;
9. whether operating expenses that we incur related to the development and commercialization of new technologies and products are effective;
10. our ability to successfully perform product development activities, the related research and development expense impact, and governmental and regulatory compliance activities, which we have not previously undertaken in any significant manner;
11. impairment of goodwill and intangible assets or the establishment of reserves against other assets on our balance sheet;
12. disruptions to our business from our plan to reduce our use of cash announced in the third quarter of fiscal 2023, the failure of such plan to achieve its objectives, or cost and expenses associated with such plan; and
13. other factors described under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022 and under "Risk Factors" in Part II, Item 1A of our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2022, which you are encouraged to read carefully.

Many of these factors are outside our control and knowledge and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon our forward-looking statements and to consult any further disclosures by us on this subject in our filings with the Securities and Exchange Commission.

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

Our investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our investments consist principally of interest-bearing corporate debt securities with varying maturity dates, which generally are less than one year. Because of the credit criteria of our investment policies, the primary market risk associated with these investments is interest rate risk. As of June 30, 2023, we did not hold any available-for-sale debt securities. Therefore, interest rate fluctuations relating to investments would have an insignificant impact on our results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of funds in cash and cash equivalents, which are defined as financial instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements and commercial paper instruments.

Loans under the Midcap credit agreement bear interest at floating rates tied to Term SOFR. As a result, changes in Term SOFR can affect our results of operations and cash flows to the extent we do not have effective interest rate swap arrangements in place. On October 14, 2022, we entered into a five-year interest rate swap transaction with Wells Fargo Bank, N.A. with respect to $25.0 million of notional value of the term loans funded under the MidCap credit agreement. The interest rate swap transaction fixes at 4.455% the one-month Term SOFR portion of interest rate under the $25.0 million initial Term Loan funded such that the interest rate on $25.0 million of the Term Loan will be 10.205% through its maturity. We have no other swap arrangements in place for any other loans under the Midcap credit agreement.

Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

We are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening relative to the Euro, our revenue and expenses denominated in Euro currency are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. All sales transactions are denominated in U.S. dollars or Euros. We generate royalties revenue from the sale of customer products in foreign jurisdictions. Royalties generated in foreign jurisdictions by customers are converted and paid in U.S. dollars per contractual terms. Substantially all of our purchasing transactions are denominated in U.S. dollars or Euros. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange rates.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of June 30, 2023. Based on that evaluation, the Company's Certifying Officers concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

**Changes in Internal Controls over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, the Company has been involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes.

### Item 1A. Risk Factors

The risks identified in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022, filed with the Securities and Exchange Commission on November 23, 2022, under Part I, Item 1A, “Risk Factors” and the risks identified in our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2022, filed with the SEC on February 6, 2023, under Part II, Item 1A, “Risk Factors” could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report on Form 10-Q.

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

The following table presents the information with respect to purchases made by or on behalf of Surmodics, Inc. or any “affiliated purchaser” (as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934), of our common stock during the three months ended June 30, 2023.

| | Total Number of Shares Purchased (1) | Average Price Paid Per Share | Total Number of Shares Purchased as Part of Publicly Announced Programs | Maximum Dollar Value of Shares that May Yet Be Purchased Under the Programs |
|---|---|---|---|---|
| Period: | | | | |
| April 1 – 30, 2023 | — | $ — | — | $ 25,300,000 |
| May 1 – 31, 2023 | 804 | 20.23 | — | 25,300,000 |
| June 1 – 30, 2023 | — | — | — | 25,300,000 |
| Total | 804 | 20.23 | — | |

(1) All shares reported were delivered by employees in connection with the satisfaction of tax withholding obligations related to the vesting of shares of restricted stock.

The Company has an aggregate of $25.3 million available for future common stock purchases under the current authorizations. The MidCap credit agreement restricts our ability to repurchase our common stock.

### Item 3. Defaults Upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not Applicable.

### Item 5. Other Information

None.

**Item 6. Exhibits**

**EXHIBIT INDEX**

| Exhibit | Description |
|---|---|
| 2.1 | Agreement of Merger dated January 18, 2005 among Surmodics, Inc., SIRx, InnoRx, et al. — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 24, 2005. |
| 2.2 | Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated November 27, 2015. |
| 2.3 | Stock Purchase Agreement, dated January 8, 2016, among Surmodics, Inc. and the shareholders of NorMedix, Inc. and Gregg Sutton as Seller's Agent — incorporated by reference to Exhibit 2.1 to the Company's Form Current Report on Form 8-K filed on January 13, 2016. |
| 2.4 | Share Purchase Agreement by and among Surmodics, Inc., SurModics MD, LLC, and the shareholders of Vetex Medical Limited named therein dated as of July 2, 2021 — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated July 2, 2021. |
| 2.5 | Put and Call Option Agreement by and among SurModics MD, LLC and the shareholders of Vetex Medical Limited named therein dated as of July 2, 2021 — incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K dated July 2, 2021. |
| 3.1 | Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2016. |
| 3.2 | Restated Bylaws of Surmodics, Inc., as amended July 20, 2023 — incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed on July 26, 2023. |
| 31.1* | Certification of Chief Executive Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Chief Financial Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Chief Executive Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2* | Certification of Chief Financial Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS* | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the inline XBRL document. |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema. |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase. |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase. |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase. |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase. |
| 104* | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101). |

* Filed herewith

**SIGNATURES**

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

August 2, 2023

**Surmodics, Inc.**

By: /s/ Timothy J. Arens
Timothy J. Arens
Senior Vice President of Finance and Chief Financial Officer

(duly authorized signatory and principal financial officer)

**EXHIBIT 31.1**

**CERTIFICATION PURSUANT TO SECTION 302**
**OF THE SARBANES-OXLEY ACT OF 2002**

I, Gary R. Maharaj, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Surmodics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 2, 2023

Signature: /s/ Gary R. Maharaj

Gary R. Maharaj
President and
Chief Executive Officer

**EXHIBIT 31.2**

**CERTIFICATION PURSUANT TO SECTION 302**
**OF THE SARBANES-OXLEY ACT OF 2002**

I, Timothy J. Arens, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Surmodics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 2, 2023

Signature: /s/ Timothy J. Arens

Timothy J. Arens

Senior Vice President of Finance and Chief Financial Officer

**EXHIBIT 32.1**

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

In connection with the Quarterly Report of Surmodics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission (the "Report"), I, Gary R. Maharaj, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: August 2, 2023

Signature: /s/ Gary R. Maharaj

Gary R. Maharaj
President and
Chief 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 of Surmodics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission (the "Report"), I, Timothy J. Arens, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: August 2, 2023

Signature: /s/ Timothy J. Arens

Timothy J. Arens
Senior Vice President of Finance and Chief Financial Officer