



SURMODICS

Surmodics, Inc.

Annual Report on

Form 10-K

for the fiscal year ended
September 30, 2024

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

FORM 10-K

(Mark One)

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

For the fiscal year ended September 30, 2024

OR

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

For the transition period from _____ to _____

Commission File Number 0-23837

Surmodics, Inc.

(Exact name of Registrant as specified in its Charter)

Minnesota

(State or other jurisdiction of
incorporation or organization)

41-1356149

(I.R.S. Employer
Identification No.)

9924 West 74th Street
Eden Prairie, Minnesota

(Address of principal executive offices)

55344

(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.05 par value	SRDX	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES NO

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>		
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>	Emerging growth company	<input type="checkbox"/>

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant as of March 31, 2024 was approximately \$401 million (based on the closing price of the Registrant's Common Stock on such date).

The number of shares of Registrant's Common Stock outstanding as of November 15, 2024 was 14,326,000.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the Registrant's 2025 Annual Meeting of Shareholders may be incorporated by reference into Part III of this Annual Report on Form 10-K. If the Registrant determines to not file a Proxy Statement as a result of the pendency of the proposed merger with BCE Parent, LLC, the Company will file an amendment to this Annual Report on Form 10-K that includes such Part III information.

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Forward-looking Statements

Certain statements contained in this Form 10-K, or in other reports of Surmodics, Inc. (the “Company”) and other written and oral statements made from time to time by the Company, do not relate strictly to historical or current facts. As such, they are considered “forward-looking statements” that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, expectations related to the Merger Agreement among the Company BCE Parent, LLC, a Delaware limited liability company (“Parent”), and BCE Merger Sub, Inc., a Minnesota corporation and a wholly owned Subsidiary of Parent (“Merger Sub”) (the “Merger Agreement”), pursuant to which the Company will, subject to the terms and conditions of the Merger Agreement, be acquired by Parent through the merger of Merger Sub with and into the Company (the “Merger”); our strategies for growth, including our ability to sign new license agreements, conduct clinical evaluations, complete process and manufacturing validations, and bring new products to market; statements regarding growing revenues associated with the adoption, utilization and sales of our Pounce™ and Sublime™ product platforms; planned limited market evaluations or commercial launches for our products; the development of future products and their anticipated attributes; regulatory submissions and approvals; the ability of our thrombectomy devices to achieve rapid growth in large, under-penetrated markets and improve clinical outcomes and reduce healthcare costs; the ability of our *Sublime* device portfolio is uniquely positioned to lead the market for dedicated devices that facilitate a radial-to-peripheral approach to vascular intervention procedures; the ability of our vascular intervention products to be competitive and to demonstrate improvements in patient outcomes; the strong future potential for our drug-delivery coatings to improve the function of a medical device, which itself is necessary to treat a medical condition, enable site-specific drug delivery while limiting systemic exposure, and enhance the biocompatibility of a medical device to ensure that it continues to function over a long period of time; expectations related to revenue, product revenue, and license fee revenue from of our SurVeil™ drug-coated balloon (“DCB”) products; future revenue growth, our longer-term valuation-creation strategy, and our future potential; future opportunities and goals related to new product offerings; future product gross profits and gross margins; estimated future amortization expense; expectations regarding operating expenses and interest expense; recognition of unrecognized compensation costs; anticipated patent expirations; research and development plans and expenses; expectations regarding clinical follow up and completion of the TRANSCEND trial and its impact on recognition of *SurVeil* DCB license fee revenue; anticipated cash requirements; future cash flow and sources of funding, and their ability together with existing cash, cash equivalents, and investments to provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for the next twelve months; the availability of funds under our debt arrangements; expectations regarding declaring or paying dividends; plans regarding our securities investments and the potential impact of interest rate fluctuations; expectations regarding the maturity of debt; the impact of potential lawsuits or claims; where our manufacturing activities will take place for various categories of products; the impact of potential change in raw material prices, sources of raw materials and our ability to manufacture raw materials ourselves; the possibility that we will be required to record adjustments to the valuation allowance in future reporting periods; the impact of Abbott Vascular, Inc. (“Abbott”) and Medtronic plc, as well as other significant customers; our ability to recognize the expected benefits of our acquisitions; our strategic transformation to become a provider of vascular intervention medical device products; future income tax expense (benefit); when tax loss carryforwards and credits begin to expire; the future impact of off-balance sheet arrangements and contractual obligations; 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 this Annual Report on Form 10-K. 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. risks related to the consummation of the Merger, including the risks that (a) the Merger may not be consummated within the anticipated time period, or at all, (b) the parties may fail to secure the termination or expiration of any waiting period applicable under Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the “HSR Act”), (c) other conditions to the consummation of the Merger under the Merger Agreement may not be satisfied, (d) all or part of Parent’s financing may not become available, and (e) the significant limitations on remedies contained in the Merger Agreement may limit or entirely prevent the Company from specifically enforcing Parent’s obligations under the Merger Agreement or recovering damages for any breach by Parent;

2. the effects that any termination of the Merger Agreement may have on the Company or its business, including the risks that (a) the Company's stock price may decline significantly if the Merger is not completed, (b) the Merger Agreement may be terminated in circumstances requiring the Company to pay Parent a termination fee of \$20,380,000, or (c) the circumstances of the termination, including the possible imposition of a 12-month tail period during which the termination fee could be payable upon certain subsequent transactions, may have a chilling effect on alternatives to the Merger;
3. the effects that the announcement or pendency of the Merger has had and may have on the Company and its business, including the risks that as a result (a) the Company's business, operating results or stock price may suffer, (b) the Company's current plans and operations may be disrupted, (c) the Company's ability to retain key employees has been, and may continue to be, adversely affected, (d) the Company's ability to recruit key employees may be adversely affected, (e) the Company's business relationships (including, customers, franchisees and suppliers) may be adversely affected, or (f) the Company's management's or employees' attention may be diverted from other important matters;
4. the effect of limitations that the Merger Agreement places on the Company's ability to operate its business, return capital to shareholders or engage in alternative transactions;
5. the nature, cost and outcome of pending and future litigation and other legal proceedings, including any such proceedings related to the Merger and instituted against the Company and others;
6. the risk that the Merger and related transactions may involve unexpected costs, liabilities or delays;
7. ongoing operating losses, interest expense, and failure to generate cash flows from operations, which could impact expected expenditures and investments in growth initiatives;
8. 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 revenue we derive;
9. the anticipated decline in fiscal 2025 in our revenue from the sales of *SurVeil* DCB products and the risk that Abbott's revenue from the sale of *SurVeil* DCB products will be less than we anticipated when we recognized profit-sharing revenue on our sale of those *SurVeil* DCB products to Abbott;
10. our ability to successfully develop, obtain regulatory approval for, commercialize, and manufacture at commercial volumes our DCB products under development, including our reliance on clinical research organizations to manage clinical trials and uncertainty related to the impacts of any clinical research relative to DCB products;
11. 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;
12. our ability to successfully and profitably commercialize our vascular intervention products, including our *Pounce* Venous Thrombectomy System, through our direct salesforce, or otherwise;
13. our ability to comply with the covenants in our credit facility;
14. 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;
15. whether operating expenses that we incur related to the development and commercialization of new technologies and products are effective;
16. our ability to successfully perform product development activities, the related research and development expense impact, and governmental and regulatory compliance activities, with which we do not have extensive experience;
17. impairment of goodwill and intangible assets or the establishment of reserves against other assets on our balance sheet; and
18. other factors described under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, 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 ("SEC").

PART I

ITEM 1. BUSINESS.

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 also 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.

Merger Agreement

On May 28, 2024, we entered into a Merger Agreement with BCE Parent, LLC, a Delaware limited liability company (“Parent”), and BCE Merger Sub, Inc., a Minnesota corporation and a wholly owned Subsidiary of Parent (“Merger Sub”), pursuant to which we will, subject to the terms and conditions of the Merger Agreement, be acquired by Parent for \$43.00 per share in cash through the merger of Merger Sub with and into us (the “Merger”), with Surmodics as the surviving corporation and a wholly owned subsidiary of Parent. If the Merger is consummated, shares of our common stock will be delisted from The Nasdaq Stock Market and deregistered under the Exchange Act.

The Merger was approved by Surmodics’ shareholders at a special meeting on August 13, 2024. On the same date, the Company announced that it and an affiliate of Parent each received a request for additional information and documentary materials (a “Second Request”) from the U.S. Federal Trade Commission (“FTC”) in connection with the Merger. As of the date of filing this report, the Merger remained subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act (“HSR Act”), as well as other customary closing conditions. The Company and Parent currently expect to consummate the Merger in the Company’s second fiscal quarter ending March 31, 2025, subject to customary closing conditions, including required regulatory approval. For further information on the Merger, see Note 13 “Merger Agreement” to the consolidated financial statements in “Financial Statements and Supplementary Data” in Part II, Item 8 of this Annual Report on Form 10-K.

SURMODICS’ REPORTABLE SEGMENTS:

MEDICAL DEVICE	IN VITRO DIAGNOSTICS (“IVD”)
Manufacture and licensing of performance coatings , including surface modification coating technologies to improve access, deliverability and predictable deployment of medical devices and drug-delivery coating technologies to provide site-specific drug-delivery from the surface of a medical device, with end markets that include neurovascular, peripheral, coronary, and structural heart, among others.	Manufacture of chemical and biological components used in in vitro diagnostic immunoassay and molecular tests within the diagnostic and biomedical research markets. Component products include protein stabilizers, surface coatings, substrates and antigens.
Manufacture of vascular intervention medical devices , including drug-coated balloons, mechanical thrombectomy devices, and radial access balloon catheters and guide sheaths.	

SURMODICS' PRIMARY REVENUE SOURCES:

PRODUCT SALES	ROYALTIES & LICENSE FEES	RESEARCH & DEVELOPMENT
<ul style="list-style-type: none">• IVD chemical and biological components, including protein stabilizers, surface coatings, substrates and antigens to the diagnostic and biomedical research markets (IVD segment)• Vascular intervention medical devices and related products to original equipment manufacturer suppliers and distributors, as well as directly to healthcare providers (Medical Device segment)• Performance coating reagents, the chemicals used in performance coatings by licensees (Medical Device segment)	<ul style="list-style-type: none">• Performance coating royalties and license fees from licensing of our proprietary performance coating technologies to medical device manufacturers (Medical Device segment)• SurVeil™ DCB license fees associated with upfront and milestone payments received pursuant to our Development and Distribution Agreement with Abbott Vascular, Inc. (Medical Device segment)	<ul style="list-style-type: none">• Commercial development feasibility services and contract coating services (Medical Device segment)• Commercial development services (IVD segment)

Revenue fluctuates from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our technologies; our and our customers' success in selling our vascular intervention products; the occurrence of milestone events under our development contracts; the timing of introductions of licensed products by our customers and proprietary products by us and our distributors; the timing of introductions of products that compete with our products and our customers' products; the number and activity level associated with customer development projects; the number and terms of new license agreements that are finalized; and the value of reagent chemicals, medical device and diagnostic products sold to our customers.

The information below provides an overview of the principal products, services and markets for each of our two reportable segments. The discussion of other aspects of our business, including patents and proprietary rights, significant customers, manufacturing, government regulation, and our human capital, applies to our business in general, and we describe material segment information within these sections where relevant.

MEDICAL DEVICE SEGMENT

Our Medical Device segment consists of two interrelated product platforms:

- **Vascular Intervention Medical Devices.** We develop and manufacture our own proprietary vascular intervention medical device products, which leverages the combination of our expertise in proprietary surface modification and drug-delivery coating technologies, along with our device design, development and manufacturing 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 medical device products than we would by licensing our device-enabling technologies.
- **Performance Coatings.** Surmodics is an established market leader in proprietary surface modification coating technologies that impart lubricity, pro-healing and biocompatibility characteristics, as well as drug-delivery capabilities (together, "performance coatings" or "performance coating technologies") to medical devices and delivery systems. We develop and commercialize our performance coatings through license agreements with medical device manufacturers for use in their medical devices.

Our strategy is to develop a portfolio of highly differentiated medical devices for vascular interventional treatment. We invest in the development and commercialization of devices that serve large, under-penetrated markets; address unmet clinical needs; improve clinical outcomes for patients; and reduce procedure costs. Our portfolio and pipeline of vascular intervention medical device products includes the following primary platforms:

- **Drug-coated balloons** (“DCBs”) which combine a pharmaceutical drug with a medical device to treat narrowing of the blood vessels supplying the extremities (most commonly in the legs), known as peripheral artery disease (“PAD”);
- **Mechanical thrombectomy devices** to remove clots from arteries and veins in the peripheral arterial and venous vasculatures; and
- **Radial access devices** to enable access and treatment of stenosed (narrowed) arteries from the thigh to the foot via radial (wrist) access, and which can also be used in alternative access sites, including femoral and pedal access.

In addition to these primary platforms, our device manufacturing operations include:

- **Specialty catheters.** We have successfully developed, received U.S. and European Union (“E.U.”) regulatory approvals, and executed commercialization partnerships for several specialty catheter products. We have partnered with Medtronic plc (“Medtronic”) to distribute our *Telemark* microcatheter in the U.S. and Europe for coronary applications. We have partnered with Cook Medical to distribute our 0.014” and 0.018” low-profile percutaneous transluminal angioplasty (“PTA”) balloon catheters in the U.S. and Europe.

In addition, we leverage our proprietary balloon catheter technology to deliver contract-manufactured balloon catheter products to original equipment manufacturers (“OEMs”) on a limited scale.

We commercialize our medical device products using two strategies:

- **Direct sales.** We have a direct salesforce, which was established in fiscal 2022, that sells our mechanical thrombectomy and radial access devices directly to healthcare providers.
- **Strategic partnerships.** For certain of our products, including our DCB products, our clinical development and commercialization strategy utilizes distribution partnerships with large, strategic medical device companies. The exclusive distribution partner for our *SurVeil* DCB is Abbott Vascular, Inc.

For all of our products under development, as further described under the caption “Government Regulation” below, the expected timing and potential success of regulatory approval and commercialization for the products pending regulatory approval can vary greatly given the significant uncertainty inherent in the product development and regulatory approval processes.

Vascular Intervention Medical Devices – Drug Coated Balloons (“DCBs”)

MEDICAL DEVICE SEGMENT

We have leveraged our performance coating technologies to successfully develop multiple DCB devices for use in vascular interventions for the treatment of PAD. DCBs are used by physicians to expand the diameter (lumen) of a narrowed vessel, thus improving or restoring blood flow. The drug coating helps to prevent the vessel from narrowing again (restenosis) after treatment. PAD is a serious and under-diagnosed circulatory condition caused by build-up of plaque, most commonly in the legs. Over 8 million Americans are affected by PAD, which increases risk of coronary artery disease, heart attack and stroke. PAD can impair the ability to walk and, if left untreated, can lead to gangrene and limb amputation.

The following is a brief description of each of these devices and their stage of clinical development, with additional information about each device provided further below.

- ***SurVeil* DCB** is a paclitaxel-coated DCB to treat PAD in the upper leg (superficial femoral artery). 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. In June 2023, the *SurVeil* DCB received U.S. Food and Drug Administration (“FDA” or the “Agency”) premarket approval (“PMA”) and may now be marketed and sold in the U.S. by our exclusive distribution partner, Abbott Vascular, Inc. (“Abbott”), under our exclusive worldwide distribution agreement.

In the first quarter of fiscal 2024, we completed shipment of Abbott’s initial stocking order of commercial units of the *SurVeil* DCB, resulting in recognition of product sales. Beginning in January 2024, the *SurVeil* DCB is a commercial product available in the U.S. through Abbott. Throughout fiscal 2024, we continued to manufacture and ship commercial units to Abbott in support of Abbott’s commercialization of the product.

- **Sundance™ DCB** is a sirolimus-coated DCB used for the treatment of below-the-knee PAD, including critical limb ischemia (“CLI”). Our SWING first-in-human, 35-patient, 36-month clinical study was designed to evaluate the safety and performance of our *Sundance* DCB when used to treat occlusive disease of the infra-popliteal arteries. SWING study data at 24 months demonstrated an excellent safety profile and promising signals of potential performance. We continue 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 and market interest.

Our DCB products are required to go through clinical studies in order for us to obtain regulatory approval or clearance to market the product in the U.S. Each clinical study includes one or more primary endpoints, which measure the effectiveness and/or safety of a device based on the product’s ability to achieve one or more pre-specified outcomes. Primary endpoints are selected based on the proposed intended use of the medical device. A pivotal trial is a definitive study designed to gather evidence to evaluate the safety and effectiveness of a product prior to its marketing.

***SurVeil* DCB.** Our *SurVeil* DCB product is a paclitaxel-coated DCB to treat PAD in the upper leg (superficial femoral artery). The *SurVeil* DCB is a next-generation device that utilizes best-in-class technology for the treatment of PAD, including a proprietary paclitaxel drug-excipient formulation for a durable balloon coating manufactured using an innovative process to improve coating uniformity. The design of the *SurVeil* DCB is intended to provide more uniform drug distribution, better efficiency of drug transfer, and fewer downstream particulates and downstream embolization.

Our *SurVeil* DCB product has the necessary regulatory approval for commercialization in the U.S. (PMA from the FDA was received in June 2023). Beginning in January 2024, the *SurVeil* DCB is a commercial product available in the U.S. through Abbott. Throughout fiscal 2024, we continued to manufacture and ship commercial units to Abbott in support of Abbott’s commercialization of the product.

TRANSCEND Pivotal Clinical Trial. The TRANSCEND pivotal clinical trial has been used to support the regulatory approval for the *SurVeil* DCB in the U.S. by providing the data necessary to evaluate the safety and effectiveness of our *SurVeil* DCB compared with the Medtronic IN.PACT® Admiral® DCB in treating PAD in the upper leg (superficial femoral artery). The trial enrolled 446 subjects at 65 global sites. The trial’s primary efficacy endpoint is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization through 12 months post-index procedure. TRANSCEND enrollment was completed in fiscal 2019, and all randomized subjects will be followed through 60 months post-index procedure.

- In January 2021, we announced the TRANSCEND 12-month pivotal clinical trial met both the primary safety and primary efficacy endpoints, and the *SurVeil* DCB was found to be non-inferior in those endpoints to the Medtronic IN.PACT® Admiral® DCB, while delivering a substantially lower drug dose.
- TRANSCEND 36-month data demonstrated comparable, sustained clinical outcomes between the *SurVeil* DCB and IN.PACT® Admiral® DCB cohorts through 36 months, including rates of clinically driven target lesion revascularization, major limb amputation, thrombosis at the target lesion, and major adverse events.

Abbott Agreement. In fiscal 2018, we entered into a Development and Distribution Agreement with Abbott (the “Abbott Agreement”), which provided Abbott with exclusive worldwide commercialization rights for the *SurVeil* DCB.

- Pursuant to the terms of the Abbott Agreement, the Company has received upfront and milestone payments totaling \$87.8 million as of September 30, 2024. These payments are recognized as *SurVeil* DCB license fee revenue as costs are incurred over the five-year TRANSCEND pivotal clinical trial. There are no additional potential milestone payments available under the Abbott Agreement. We anticipate completion of the TRANSCEND pivotal clinical trial in the second quarter of fiscal 2025; consequently, we expect no further recognition of *SurVeil* DCB license fee revenue subsequent to March 31, 2025.
- Under the Abbott Agreement, we supply commercial units of the *SurVeil* DCB to Abbott, and Abbott has exclusive worldwide distribution rights. Upon shipment of *SurVeil* DCB units to Abbott, we recognize product revenue, which includes (i) an agreed-upon transfer price and (ii) a share of net profits resulting from product sales by Abbott to third parties. In the first quarter of fiscal 2024, we completed shipment of Abbott’s initial stocking order of commercial units of the *SurVeil* DCB, and throughout fiscal 2024, we continued to manufacture and ship commercial units to Abbott in support of Abbott’s commercialization of the product.
- Surmodics is responsible for conducting all necessary clinical trials and other activities required to obtain and maintain U.S. and E.U. regulatory clearances for the *SurVeil* DCB, including completion of the ongoing TRANSCEND pivotal clinical trial. Expenses related to these activities are paid by Surmodics. Abbott and Surmodics participate on a joint development committee charged with providing guidance on the Company’s clinical and regulatory activities related to the *SurVeil* DCB product.

Sundance DCB. Our sirolimus-coated *Sundance* DCB is used for the treatment of below-the-knee PAD, including CLI. CLI is estimated to impact between 2.1 million and 3.8 million Americans, a number that could grow to between 2.4 million and 4.7 million by 2030. Rates of amputation and death are significant for CLI patients, and there are currently no DCB devices approved to treat the condition in the U.S.

Sirolimus has potent anti-inflammatory and anti-proliferative effects to inhibit cell division, without creating vascular toxicity, and has a proven history of safety and efficacy in vascular anatomy. We leveraged our expertise in performance coatings in the innovative design of our *Sundance* DCB, which in pre-clinical benchtop and animal testing has shown clear advantages over competitive technologies, including superior drug coating durability, higher levels of drug transfer, and a unique ability to achieve sustained therapeutic levels in the tissue.

Below is a summary of our clinical and regulatory progress related to the *Sundance* DCB.

- In October 2019, the FDA designated the *Sundance* DCB as a “Breakthrough Device” under the FDA’s Breakthrough Devices Program, which is designed to streamline the market clearance/approval process for products that have the potential to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.
- Our SWING first-in-human, 35-patient, 36-month clinical study was designed to evaluate the safety and performance of our *Sundance* DCB when used to treat occlusive disease of the infra-popliteal arteries. Enrollment and six-month follow up visits were completed in fiscal 2021. The clinical report for the SWING study was completed in fiscal 2022, which demonstrated promising early safety data and performance insights. SWING study data demonstrated an excellent safety profile at 24 months, with no major amputations and low rates of major adverse events. There were no clinically driven target lesion revascularizations in study participants between six- and 24-months post procedure. SWING study data also showed promising signals of potential performance of the device, with target lesion primary patency maintained in 80% of per protocol patients at 12 months and in 71% of per protocol patients at 24 months.

We continue 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 and market interest.

Vascular Intervention Medical Devices – Mechanical Thrombectomy

MEDICAL DEVICE SEGMENT

We have successfully developed, internally and through acquisitions, multiple FDA 510(k)-cleared mechanical thrombectomy devices for the non-surgical removal of thrombi and emboli (clots) from the peripheral arterial and venous vasculatures, while minimizing the need for thrombolytics. We believe that the ease of use, intuitive design and performance of our thrombectomy systems make these devices attractive first-line treatment options for interventionalists. These devices include:

- **Pounce™ Thrombectomy Platform**, intended for the peripheral arterial vasculature, is a suite of mechanical thrombectomy systems designed for the capture and non-surgical removal of thrombi and emboli (clots) without the need for capital equipment or aspiration while minimizing the use of thrombolytics. During fiscal 2022, we established a direct salesforce and commenced commercial sales of our *Pounce* Thrombectomy Platform to hospitals and clinics.
- **Pounce Venous Thrombectomy System** is a mechanical thrombectomy system indicated for mechanical de-clotting and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral vasculature. The *Pounce* Venous Thrombectomy System is designed to remove mixed-morphology, wall-adherent venous clot in a single session, minimizing the need for thrombolytics and without the need for capital equipment. We conducted limited market evaluations of the *Pounce* Venous Thrombectomy System in fiscal 2023 and in the first half of fiscal 2024 to obtain physician feedback across a variety of cases and clinical conditions. In the second quarter of fiscal 2024, we completed limited market evaluations for the *Pounce* Venous Thrombectomy System, and the product was commercially launched.

Our thrombectomy devices represent a core offering within our vascular intervention product strategy, providing the opportunity for:

- Rapid growth in large, under-penetrated markets; and
- Improved clinical outcomes and reduced healthcare costs, with single session treatment for removal of difficult clots, no capital equipment, and the potential to reduce the need for thrombolytic drugs.

Peripheral arterial occlusion (“PAO”), the blocking of arteries by clots, is a peripheral vascular condition commonly associated with CLI. Often, these arterial clots require surgical intervention and have proven difficult to remove with currently available medical device technologies. Depending on the age and magnitude of the occlusion and the viability of the threatened limb, existing treatments for this condition may include catheter-directed thrombolysis, surgical embolectomy, and/or percutaneous mechanical thrombectomy. In cases in which the occlusion has caused irreversible damage to the limb, acute limb ischemia can result in the amputation of a lower extremity.

Venous thromboembolism (“VTE”), a blood clot in the veins, is an under-diagnosed and serious, yet treatable, medical condition that can cause disability and death. VTE affects approximately 1.2 million U.S. patients each year. The current standard of care for treating VTE is conservative medical management with anticoagulant drugs designed to prevent further blood clotting. While anticoagulation remains the most widespread therapy for VTE, interventional treatment has demonstrated the potential for better outcomes in select patients.

We believe our proprietary *Pounce* Thrombectomy and *Pounce* Venous thrombectomy devices provide physicians with the opportunity to remove peripheral arterial and venous clots in a more effective, cost-efficient manner than other currently available treatments. The devices offer innovative designs that may reduce the need for the use of thrombolytic drugs. Thrombolytic drugs are often associated with complications, which can include bleeding complications, longer hospital stays and higher cost of treatment. Our *Pounce* Thrombectomy and *Pounce* Venous thrombectomy devices are designed to reduce procedure time, efficiently remove large volumes of clot, and eliminate the need for additional external capital equipment, thereby providing an easy-to-use, on-the-table, single-session solution for clinicians.

***Pounce* Thrombectomy Platform**, intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature, is a suite of mechanical thrombectomy systems designed to remove clots without the need for capital equipment or aspiration while minimizing the use of thrombolytics. Three different-sized systems are commercially available.

- The original *Pounce* (mid profile) Thrombectomy System is indicated for use in peripheral arterial vessels 3.5 mm to 6 mm in diameter, such as those found above the knee. Commercial sales of the *Pounce* Thrombectomy System began in fiscal 2022.
- The *Pounce* LP (Low Profile) Thrombectomy System is indicated for use in peripheral arterial vessels 2 mm to 4 mm in diameter, such as those found below the knee. The *Pounce* LP Thrombectomy System received FDA 510(k) regulatory clearance in the third quarter of fiscal 2023, and we began limited market evaluations of the product in the first quarter of fiscal 2024. In the third quarter of fiscal 2024, we completed limited market evaluations for the *Pounce* LP Thrombectomy System, and the product was commercially launched.
- The *Pounce* XL Thrombectomy System is indicated for use in peripheral arterial vessels 5.5 mm to 10 mm in diameter, making it suitable for iliac, femoral, and other arteries within this range. The *Pounce* XL Thrombectomy System received FDA 510(k) regulatory clearance in the fourth quarter of fiscal 2024. We plan to initiate limited market evaluations of the product in the first half of fiscal 2025, with commercialization following the completion of the limited market release.

The *Pounce* Thrombectomy Platform device systems consist of three components: a 5 Fr basket delivery catheter, a basket wire, and a funnel assembly. After the basket wire is delivered distal to the location of the thrombus, two nitinol self-expanding baskets are deployed to collect and entrain the clot into a funnel-shaped nitinol wire mesh. With the clot entrained, the funnel assembly is then collapsed into a 7 Fr procedure guide sheath through which the clot is withdrawn and removed from the body. Physician feedback indicates the *Pounce* Thrombectomy Platform device systems are capable of achieving positive outcomes with minimal blood loss and with minimal use of thrombolytics. The devices offer an intuitive, grab-and-go design to simplify setup and reduce the physician’s learning curve.

***Pounce* Venous Thrombectomy System.** Our *Pounce* Venous Thrombectomy System, which received FDA 510(k) clearance in fiscal 2021, is a mechanical thrombectomy catheter for use in peripheral venous vascular beds that is specifically designed to remove large, mixed-morphology blood clots. The device’s dual-action technology features a constant spring tension basket, which provides optimal wall apposition over a range of vessel diameters, to engage and collect the clot, while the motor-driven Archimedes screw macerates and removes the collected clot. As with our *Pounce* Thrombectomy Platform devices, the *Pounce* Venous Thrombectomy System is intuitive and approachable to facilitate widespread adoption, with a low learning curve for the physician.

We acquired the venous thrombectomy device technology with our fiscal 2021 acquisition of Vetex Medical Limited (“Vetex”), which was privately held and based in Galway, Ireland. We acquired Vetex with an upfront cash payment of \$39.9 million and deferred consideration of \$1.8 million paid in fiscal 2024, with a final \$1.8 million installment of deferred consideration to be paid in fiscal 2027.

We conducted limited market evaluations of the Pounce Venous Thrombectomy System in fiscal 2023 and in the first half of fiscal 2024 to obtain physician feedback across a variety of cases and clinical conditions. In the second quarter of fiscal 2024, we completed limited market evaluations for the Pounce Venous Thrombectomy System, and the product was commercially launched.

Vascular Intervention Medical Devices – Radial Access

MEDICAL DEVICE SEGMENT

We have successfully developed and received FDA 510(k) regulatory clearance for our *Sublime*™ portfolio of devices designed for vascular intervention via radial (wrist) access that can also be used via alternative access sites, including femoral (thigh) and pedal (foot) access. Our *Sublime* devices are used to access and treat stenosed (narrowed) arteries both above and below the knee, commonly associated with PAD. During fiscal 2022, we established a direct salesforce and commenced commercial sales of our *Sublime* device portfolio to hospitals and clinics. These radial access devices include:

- ***Sublime* guide sheath** provides 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** treats lesions in peripheral arteries below the knee all the way to the patient’s foot and around the pedal loop.
- ***Sublime* .018 RX PTA dilatation catheter** treats lesions in peripheral arteries above and below the knee.
- ***Sublime* microcatheters (.014, .018 and .035)** facilitate guidewire placement for difficult to access and treat arterial lesions above and below the knee using radial, femoral, or alternate access sites. Limited market evaluations of our *Sublime* microcatheters began in the third quarter of fiscal 2023. In the third quarter of fiscal 2024, we completed limited market evaluations for the *Sublime* microcatheter, and the product was commercially launched.

Our *Sublime* device portfolio is unique in that each of these devices are purpose built for above and below the knee peripheral interventions that can employ a transradial approach *and* alternative access sites, including conventional femoral access and pedal access. Our *Sublime* guide sheath performance is enhanced by our recent generation hydrophilic coating. We believe that radial access procedures offer significant benefits by improving patient comfort, reducing recovery and ambulation times, and potentially lowering access site complications. Our *Sublime* device portfolio meets an unmet clinical need by providing longer, lower-profile devices that are robust enough to deliver treatment from the wrist all the way to the pedal loop in the foot.

We believe the *Sublime* device portfolio is uniquely positioned to lead the market for dedicated devices that facilitate a radial-to-peripheral approach. Below are a few of the unique advantages of our *Sublime* devices.

- Our *Sublime* guide sheath is the only 5F guide sheath available in a length up to 150cm, making it an ideal device for operators who seek a smaller profile sheath to help minimize radial artery spasm or to treat smaller patients when performing peripheral interventions via radial access. Physician feedback has indicated our *Sublime* guide sheath offers a low-profile design for patient comfort, superior trackability through tortuous anatomy, and resistance to kinking when compared to alternative devices.
- Our *Sublime* .014 RX PTA dilatation catheter is the longest catheter of its kind in the U.S. market, at 250 cm. Physician feedback has indicated both our *Sublime* .014 and .018 catheters provide superb deliverability and the ability to cross challenging lesions.

OVERVIEW: PERFORMANCE COATINGS

MEDICAL DEVICE SEGMENT

Surmodics’ industry-leading performance coatings are used in a minimally invasive procedure every minute of every day. Surmodics’ surface-enhancing performance coatings add differentiated value to more than 150 medical, biotechnology and pharmaceutical product families worldwide. Our customers use Surmodics’ performance coatings to enable, optimize and differentiate their device products. These performance coatings include:

- **Hydrophilic coatings** enable vascular device performance and maneuverability by reducing friction by imparting the necessary lubricity (smoothness or slipperiness) for minimally invasive, intravascular procedures. Surmodics’ low-particulate, hydrophilic coatings have a proven track record, meeting demanding regulatory requirements in the following clinical segments: neurovascular, peripheral, coronary, and structural heart devices.
- **Drug-delivery coatings** enable a device to achieve the desired biological effect through the precisely controlled transfer of a pharmaceutical drug to targeted tissues. Surmodics possesses expertise across a range of compounds to meet a variety of clinical needs.
- **Hemocompatible coatings** improve the safety and function of devices by reducing the risk of thrombus (clot) formation actively (heparin) or passively (non-heparin).

Surmodics generates royalties and license fee revenue by licensing our performance coating technologies to medical device manufacturers, product revenue from sales to licensees of the chemical reagents used in coatings, and R&D revenue from commercial development feasibility services and contract coating services.

Our performance coatings are differentiated by their flexibility, durability and ease of use. In terms of flexibility, coatings can be applied to many kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents. Additionally, the surface modification process can be tailored to provide customers with the ability to improve their devices' performance by choosing the specific coating properties desired for particular applications. Our performance coating technologies can also be combined to deliver multiple surface-enhancing characteristics on the same device.

The continuing trend toward minimally invasive surgical procedures, which often employ catheter-based delivery technologies, has increased the demand for hydrophilic (i.e., lubricious or slippery) coatings and other coating technologies, including drug-delivery coatings. For example, stents, particularly drug-eluting stents, have significantly reduced the need for repeat intravascular procedures or more invasive cardiac bypass surgery. Transcatheter heart valve repair, or replacement via a minimally invasive catheter-based system, has enabled the treatment of patients suffering from heart valve disease who are too ill to undergo open-heart surgery.

Hydrophilic Coatings. Our proprietary PhotoLink™ coating technology ("*PhotoLink* Technology") is a versatile, easily applied, coating technology that modifies medical device surfaces by creating covalent bonds between device surfaces and a variety of chemical agents. *PhotoLink* Technology can impart many performance-enhancing characteristics, such as advanced lubricity (slipperiness or smoothness) and hemocompatibility (preventing blood clot formation), when bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or other physical properties of devices.

PhotoLink Technology reagents can be applied to a range of substrates. The coating formulations are easily applied to the material surface by a variety of methods including, but not limited to, dipping, spraying, roll-coating and ink-jetting. We continue to expand our proprietary reagent portfolio for use by our customers. These reagents enable our customers to develop novel surface features for their devices, satisfying the expanding healthcare industry requirements. We are also continually working to expand the list of materials that are compatible with our surface modification and device drug-delivery reagents. Additionally, we develop coating processes and coating equipment to meet the device quality, manufacturing throughput, and cost requirements of our customers.

The *PhotoLink* Technology coating process is relatively simple to use and is easily integrated into the customer's manufacturing operations. In addition, the process does not subject the coated products to harsh chemical or temperature conditions, produces no hazardous byproducts, and does not require lengthy processing or curing time. Further, coatings incorporating the *PhotoLink* Technology are generally compatible with accepted sterilization processes, so the surface attributes are not lost when the medical device is sterilized.

Our Serene™ hydrophilic coating platform, which uses our *Photolink* Technology, improves lubricity and durability, while significantly reducing particulates generation. This *PhotoLink* Technology-enabled coating has demonstrated excellent lubricity on a wide range of substrates and has been used on FDA-cleared coronary, peripheral and structural heart devices.

In October 2023, we announced the commercial launch of our most advanced hydrophilic medical device coating technology, *Preside*™ hydrophilic coatings. *Preside* hydrophilic coatings complement our existing *Serene* hydrophilic coatings by providing customers with a unique low-friction and low-particulate generation coating to further enhance distal access for neuro-vascular applications, as well as improved crossing for challenging coronary lesions or chronic total occlusions. *Preside* hydrophilic coatings are specifically formulated to meet the challenge of achieving the right balance of enhanced lubricity (reduction in friction) and excellent coating durability (resulting in low particulates) for the next generation of neurovascular, coronary and peripheral vascular devices. Our *Preside* and *Serene* hydrophilic coatings both allow customers to leverage their existing coating process to apply these innovative surface treatments.

Drug-delivery Coatings. Our device drug-delivery coating technologies allow therapeutic drugs to be incorporated within our proprietary polymer matrices to provide controlled, site-specific release of the drug into the surrounding environment. The drug release can be tuned to elute quickly (within minutes to a few days) or slowly (from several months to over a year), illustrating the wide range of release profiles that can be achieved with our coating systems. On a wide range of devices, drug-eluting coatings can help improve device performance, increase patient safety, and enable innovative new treatments. DCBs are a typical example of short-term use drug-delivery devices. An example of longer-term drug-delivery devices is drug-eluting stents. We work with companies in the medical device and biotechnology industries to develop specialized coatings that allow for the controlled release of drugs from device surfaces. We see at least three primary areas with strong future potential:

(1) improving the function of a device which itself is necessary to treat the medical condition;

- (2) enabling site-specific drug delivery while limiting systemic exposure; and
- (3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

Performance Coatings – Licensing Arrangements

MEDICAL DEVICE SEGMENT

We commercialize our performance coating technologies primarily through licensing arrangements with medical device manufacturers. We believe this approach allows us to focus our resources on further developing new technologies and expanding our licensing activities. Many of our technologies have been designed to allow manufacturers to implement them easily into their own manufacturing processes so customers can control production and quality internally without the need to send their products to a contract manufacturer. We generate the largest proportion of our revenue through licensing arrangements. Revenue from these licensing arrangements typically includes royalties based on a percentage of licensees' product sales, with a contractual minimum, and license fees upon achievement of regulatory and commercialization milestones. Royalties and license fee revenue from our performance coatings represented 30%, 25% and 31% of our total revenue in fiscal 2024, 2023 and 2022, respectively. In each of fiscal 2024, 2023 and 2022, we saw double-digit year-over-year growth in revenue associated with our *Serene* hydrophilic coating technology driven by customer product launches and resulting market share increases associated with the customer device applications that incorporate the *Serene* coating technology.

The licensing process for our performance coating technologies begins with the customer specifying a desired product feature to be created, such as lubricity or drug delivery. Because each device and coating application is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating commercial development revenue. Feasibility studies can range in duration from several months to a year. After we complete a feasibility study, our customers cannot market their product until they receive regulatory approval. As further described under the caption "Government Regulation," the regulatory approval process varies in each country and ranges from several months to four or more years. At any time prior to a customer's commercial launch, a license agreement may be executed granting the licensee rights to use our technology. We often support our customers by providing coating assistance for parts required in animal tests and human clinical trials. Typically, we complete a technology transfer to most customers which enables those customers to apply the coating at their own facilities. We also generate revenue from reagent chemical product sales to licensees for use in their coating processes, as well as from providing contract coating services.

License agreement terms are generally for a specified number of years or our patent's life, whichever is longer, although a license generally may be terminated by the licensee for any reason with advance written notice. In cases where the royalty obligation extends beyond the life of the applicable patent, it is because the license also includes rights to our know-how or other proprietary rights. Under these circumstances, the royalty obligation typically continues at a reduced royalty rate for a specified number of years, generally tied to the date on which the licensee's medical device product was first sold.

Our license agreements may include certain license fees and/or milestone payments. Substantially all our licensed performance coating technology applications are nonexclusive, allowing us to license each technology to multiple customers. Moreover, even exclusive performance coating technology licenses generally are limited to a specific "field of use," allowing us the opportunity to further license technology to other customers. The royalty rate on a substantial number of the coatings agreements has traditionally been in the range of two to three percent, but there are certain contracts with lower or higher rates. In certain agreements, our royalty is based on an agreed-upon amount per unit. License fees, milestone payments, and royalty rates are based on various factors, including the licensed product's or technology's stage of development, the perceived value of our technology to the customer's product, the size of the potential market, and whether the arrangement is exclusive or nonexclusive. Our agreements often incorporate a minimum royalty to be paid by the licensee. Royalty payments generally commence one quarter after the customer's actual product sales occur because of the delay in reporting sales by our licensees. We estimate and recognize sales-based royalties revenue from our performance coating licensees in the same quarter that the underlying customer product sale occurs.

We have over 150 licensed product classes (customer products utilizing Surmodics technology) already in the market generating royalties and greater than 100 customer product classes incorporating our technology in various stages of pre-commercialization.

Under our performance coating technology license agreements, the responsibility for securing regulatory approval for and ultimately commercializing these products rests with our customers. Our reliance on our customers in this regard and the potential risks to our operations as a result are discussed in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. Moreover, we are often contractually obligated to keep the details concerning our customers' R&D efforts (including the timing of expected regulatory filings, approvals and market introductions) confidential.

Our licensing agreements generally require us to keep our customers' identities confidential, unless they approve of such disclosure. Licensed customers that allow the use of their name include: Abbott Laboratories and Abbott Vascular, Inc., Boston Scientific Corporation ("Boston Scientific"), Cook Medical, Cordis Corporation, Covidien PLC (a subsidiary of Medtronic), Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott), ev3 Inc. (a subsidiary of Medtronic), Medtronic, OrbusNeich Medical, Inc., and Spectranetics Corporation (a subsidiary of Koninklijke Philips N.V.).

Performance Coatings – R&D Services for Customers

MEDICAL DEVICE SEGMENT

For our medical device performance coating customers, we have distinct, specifically-dedicated R&D facilities and personnel to support delivery of R&D services. We work with our customers to integrate the best possible surface modification and device drug-delivery technologies with their products, not only to meet their performance requirements, but also to perform services quickly so that the product may reach the market ahead of the competition. To quickly solve problems that might arise during the development and optimization process, we offer extensive capabilities in analytical chemistry and surface characterization within our R&D organization. Our state-of-the-art instrumentation and extensive experience allow us to test the purity of coating reagents, to monitor the drug elution rate from coatings, to measure coating thickness and smoothness, and to map the distribution of chemicals throughout coatings. We believe our capabilities in this area exceed those of our competitors. Our R&D staff support our business development staff and business units in performing feasibility studies, as well as providing technical assistance to existing and potential customers. These services, which generate R&D and other revenue, include optimizing the relevant technologies for specific customer applications; supporting clinical trials; training customers; and integrating our technologies and know-how into customer manufacturing operations.

Competition

MEDICAL DEVICE SEGMENT

We are developing and commercializing differentiated vascular intervention medical devices that integrate our performance coatings, catheter, balloon and other proprietary technologies. This high degree of differentiation is strategically designed to capture market share in a highly competitive, dynamic industry. Our vascular intervention products compete with the global leaders in the vascular medical device market. We believe our vascular intervention products will be competitive on the basis of their safety and efficacy as a result of the innovative design and differentiated coating and device design technology. We believe these innovations will enable our vascular intervention products to demonstrate improvements in patient outcomes through reduced invasiveness compared to other devices used for comparable procedures.

We believe that the intense competition within the medical device market creates opportunities for our performance coating technologies as medical device manufacturers seek to differentiate their products through new enhancements or to remain competitive with enhancements offered by other manufacturers. Because a significant portion of our revenue depends on royalties and license fees derived from our customers' medical device product sales incorporating our performance coating technologies, we are also affected by competition within the markets for such devices. As we typically license our performance coating technologies on a non-exclusive basis, we benefit by offering our technologies to multiple competing manufacturers of a device. However, competition in the medical device market could also have an adverse effect on us. While we seek to license our coatings products to established manufacturers, in certain cases, our performance coating licensees may compete directly with larger, dominant manufacturers with extensive product lines and greater sales, marketing and distribution capabilities.

We also are unable to control other factors that may impact commercialization of our vascular intervention products and licensees with medical devices that utilize our performance coatings, such as regulatory approval, marketing and sales efforts of our customers and licensees, and competitive pricing pressures within the particular market. Many of our existing and potential competitors have greater financial, technical and marketing resources than we have.

The ability of performance coating technologies to improve the performance of medical devices and drugs and to enable new product categories has resulted in increased competition in these markets. Some of our competitors offer device drug-delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies target cardiovascular, peripheral or other medical device applications. In addition, because of the many product possibilities afforded by performance coatings, many of the large medical device manufacturers have developed, or are engaged in efforts to develop, internal competency in the area of performance coatings, including drug-delivery technologies.

We differentiate ourselves from our performance coatings competitors by providing what we believe is a high value-added approach. We have a proven track record of our customers successfully navigating the regulatory approval process with devices utilizing our enabling technology. We believe that the primary factors customers consider in choosing a particular technology include performance (e.g., flexibility, ability to fine tune drug elution profiles, biocompatibility), ease of manufacturing, time-to-market, intellectual property protection, ability to produce multiple products from a single process, compliance with manufacturing regulations, ability to manufacture clinical and commercial products, customer service, and total cost of goods (including manufacturing process labor). We believe our technologies deliver exceptional performance in these areas, allowing us to compete favorably with respect to these factors. With respect to our licensed performance coating technologies, we believe that the cost and time required to obtain the necessary regulatory approvals significantly reduces the likelihood of a customer changing the manufacturing process it uses once a device or drug has been approved for sale.

R&D Strategy

MEDICAL DEVICE SEGMENT

Our significant R&D investments over the past several years reflect our ongoing commitment to strengthen our proprietary product pipeline and broaden our capacity for medical device R&D activities. In fiscal 2024, 2023 and 2022, consolidated R&D expense as a percentage of consolidated revenue was 30%, 35% and 51%, respectively. In fiscal 2024, R&D expense was largely associated with our investments in vascular intervention product development; costs associated with the *SurVeil* DCB; and regulatory infrastructure, facilities and personnel. R&D expenses primarily consist of research, development, clinical and regulatory activities related to the design, development and commercialization of our products, as well as costs associated with our R&D services revenue.

We intend to continue our development efforts to expand our proprietary medical device offerings, including advancing our performance coating technologies to better meet these needs across multiple medical markets and to capture more of the final product value. We anticipate R&D expenses will continue to be significant in fiscal 2025 and beyond, primarily related to medical device product development, including continued investment in our thrombectomy and radial access platforms.

To strengthen our licensing business model, R&D personnel and facilities for our *Pounce* thrombectomy and *Sublime* radial access vascular intervention products are fully segregated from those for our performance coatings to preserve confidential information of our coatings customers (licensees). In our Medical Device segment, we conduct manufacturing and R&D in multiple facilities. Two of those separate facilities are located in Eden Prairie, Minnesota. We also utilize external contract manufacturers for certain device products.

We have robust procedures to ensure that we protect our coatings customers' (licensees) intellectual property and avoid conflicts of interest. R&D personnel have specific roles and are part of distinct teams, clearly segregated between (i) performance coating technologies R&D, including customer development to support our licensing partnership model; and (ii) internal R&D activities to further advance our vascular intervention product portfolio. Our procedures include strict restrictions for physical access to customers' products and records and limitations on computer file access based on an R&D team member's role.

IN VITRO DIAGNOSTICS SEGMENT

Surmodics' In Vitro Diagnostics ("IVD") segment provides leading in vitro diagnostic companies with the critical components for developing sensitive, reproducible immunoassays to enable our customers' diagnostic tests to detect the absence or presence of disease. We develop, manufacture, and sell chemical and biological components for in vitro diagnostic immunoassay tests and molecular diagnostic tests for the diagnostic and biomedical research markets.

Our portfolio of IVD chemical and biological component products includes:

- **Protein Stabilizers.** We offer a full line of stabilization products for the IVD market. These products increase sensitivity and specificity and reduce false positive and false negative results, while extending the diagnostic test's shelf life, thereby producing more consistent assay results. Our stabilization products are ready-to-use, eliminating the in-house manufacturing preparation time and cost of producing stabilization and blocking reagents.
- **Surface Coatings for Molecular Diagnostic Applications.** We offer custom coatings for molecular diagnostic applications, including DNA, RNA and protein microarrays. Our TRIDIA™ surface coatings bind molecules to a variety of surfaces and geometries and may be customized for selectivity using passivating polymers and reactive groups. This proprietary technology immobilizes DNA and protein to adhere to testing surfaces. We offer other surface coatings that improve flow characteristics through membranes and microfluidic channels on diagnostic devices, including point-of-care components.

- **Substrates.** We provide colorimetric and chemiluminescent substrates to the IVD market under our BioFX® trademark. A substrate is the diagnostic test kit component that detects and signals that a reaction has taken place so that a result can be recorded. Colorimetric substrates signal a positive diagnostic result through a color change. Chemiluminescent substrates signal a positive diagnostic result by emitting light. We believe that our substrates offer a high level of stability, sensitivity and consistency.
- **Antigens and Antibodies.** We are the exclusive distributor in the U.S., Canada and Puerto Rico (and non-exclusive distributor in Japan) of the BBI Solutions' DIARECT™ line of antigens and antibodies ("DIARECT"). DIARECT produces the majority of these antigens and antibodies using recombinant technology.

Our IVD products address the following customer needs:

- **Immunoassay Diagnostics.** Surmodics develops, manufactures and sells high-performing, consistent-quality and stable immunoassay component products to enable our customers' diagnostic tests to detect the absence or presence of disease. An immunoassay is a biochemical test that measures the presence or concentration of a target molecule, or analyte, in a biological fluid or sample. Analyte levels are correlated to the patient's disease state or medical condition to diagnose the presence, absence or severity of disease. Analytes can range from large molecules such as proteins to small molecules such as hormones. Immunoassays are developed and produced using multiple components. The component's selection and optimization confer the quality and performance of the assay in terms of sensitivity and specificity. IVD companies select these critical biochemical and reagent components to meet the assay's diagnostic specifications.
- **Molecular Diagnostics – DNA and Protein Immobilization.** Surmodics has developed various surface chemistries for both DNA and protein immobilization. Our TRIDIA™ product optimizes DNA, RNA, protein, and cell attachment for molecular diagnostic and immunoassay applications, reducing non-specific background and improving sensitivity. Surmodics' versatile coatings bind molecules to a variety of surfaces and geometries and may be customized for selectivity using passivating polymers and reactive groups. Both DNA and protein microarrays are useful tools for the pharmaceutical, diagnostic and research industries. During a DNA gene analysis, typically thousands of different probes need to be placed in a pattern on a surface, called a DNA microarray. These microarrays are used by the pharmaceutical industry to screen for new drugs; by genome mappers to sequence human, animal or plant genomes; or by diagnostic companies to search a patient sample for disease-causing bacteria or viruses. However, DNA does not readily adhere to most surfaces. Protein microarrays are used as diagnostic and research tools to determine the presence and/or quantity of proteins in a biological sample. The most common type of protein microarray is the antibody microarray, where antibodies are spotted onto a surface and used as capture molecules for protein detection.

Customer R&D. The sales cycle for our IVD products generally begins when an IVD company initiates the process to develop a new, or improve a current, diagnostic test. During product development, these companies seek to source the test's critical components with reagents that it produces internally or with reagents from a supplier, such as Surmodics.

As IVD tests are developed and various reagents are tested, companies will generally seek to optimize the sensitivity (false negative reductions), specificity (false positive reductions), speed (time from sample to results), convenience (ideally as few steps as possible), and cost effectiveness. Upon regulatory approval or clearance, the customer's diagnostic test can be sold in the marketplace. It may take several years after approval or clearance for the test to achieve peak market share and optimize Surmodics' revenue.

New Product R&D. Our R&D efforts to grow our IVD business segment include identifying and addressing unmet needs that exist in the global IVD marketplace. Our pipeline of IVD products includes components for immunoassay and molecular diagnostic applications, such as new protein stabilizers, detection technologies, accessory reagents and surface coatings that have the potential to add greater sensitivity, specificity, speed, convenience, and lower cost for IVD test manufacturers.

Competition. The diagnostics market is highly fragmented. In the product lines in which we compete, we face an array of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. Some of our competitors have substantially more capital resources, marketing experience, R&D resources and production facilities than we do. We believe that our products compete on performance, stability (shelf life), sensitivity (lower levels detected, faster results), consistency and price. We believe that our continued competitive success will depend on our ability to gain market share, develop or acquire new proprietary products, obtain patent or other protection for our products, and successfully market our products directly or through partners.

OTHER FACTORS IMPACTING OUR OPERATIONS

Patents and Proprietary Rights

OTHER FACTORS IMPACTING OUR OPERATIONS

Patents and other forms of proprietary rights are an essential part of Surmodics' business. We aggressively pursue patent protection covering the proprietary technologies that we consider strategically important to our business. In addition to seeking patent protection in the U.S., we also generally file patent applications in European countries and, on a selective basis, other foreign countries. We strategically manage our patent portfolio in a manner designed to ensure that we have valid and enforceable patent rights protecting our technological innovations. As of September 30, 2024, Surmodics owned or had exclusive rights to 162 issued U.S. patents and 273 issued international patents. As of the same date, we also owned or had exclusive rights to 26 U.S. pending patent applications and 65 foreign pending patent applications.

We have licensed our *PhotoLink* Technology on a non-exclusive basis to a number of our customers for use in a variety of medical device surface applications, including those described above. In particular, we have 35 issued U.S. patents, five pending U.S. patent applications, 80 issued international patents, and 10 pending international patent applications protecting various aspects of these technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and anticipated expiration dates of the patent applications range from fiscal 2025 to 2042. These patents and patent applications represent distinct families, with each family generally covering a successive generation of the technology, including improvements that enhance coating performance, manufacturability, or other important features desired by our customers. For additional details, refer to the caption "Performance Coatings – Licensing Arrangements" within this section of this Annual Report on Form 10-K.

We also rely upon trade secrets, trademarks and other un-patented proprietary technologies. We seek to maintain the confidentiality of such information by requiring employees, consultants and other parties to sign confidentiality agreements and by limiting access by parties outside the Company to such information. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of this information, or that others will not be able to independently develop such information. Additionally, there can be no assurance that any agreements regarding confidentiality and non-disclosure will not be breached, or, in the event of any breach, that adequate remedies would be available to us.

Significant Customers

OTHER FACTORS IMPACTING OUR OPERATIONS

Revenue from Abbott and Medtronic represented approximately 16% and 12%, respectively, of our consolidated revenue for fiscal 2024. Revenue from these customers was generated from multiple products and fields of use, including revenue from the Abbott Agreement, substantially all of which were recognized in our Medical Device segment. No other customer accounted for more than 8% of our consolidated revenue in fiscal 2024.

With respect to our Medical Device segment, revenue from Abbott and Medtronic represented approximately 20% and 16%, respectively, of our Medical Device segment revenue for fiscal 2024, and revenue from one additional customer represented approximately 10% of our Medical Device segment revenue for fiscal 2024. No other customer accounted for greater than 5% of Medical Device segment revenue for fiscal 2024.

With respect to our IVD segment, revenue from two customers represented approximately 24% and 11%, respectively, of our IVD segment revenue for fiscal 2024. No other customer accounted for greater than 9% of IVD segment revenue for fiscal 2024.

Manufacturing

OTHER FACTORS IMPACTING OUR OPERATIONS

We manufacture the reagent chemicals used in our performance coatings and our IVD products in one of our Eden Prairie, Minnesota facilities. In certain limited circumstances, we also provide contract manufacturing services for our customers, including, for example, coating their medical devices that are intended for pre-clinical and clinical development (including human clinical trials), and products that are sold for commercial use by our customers. We manufacture PTA balloon catheters and microcatheters in our Ballinasloe, Ireland facility, which offers a suite of capabilities, including balloon forming, extrusion, coating, braiding and assembly of finished products. We manufacture our vascular intervention products in our U.S. and Ireland facilities, and we also utilize contract manufacturers for our vascular intervention products. At our Ballinasloe, Ireland manufacturing facility, we perform a limited volume of contract manufacturing of medical devices for our customers.

We attempt to maintain multiple sources of supply for the key raw materials used to manufacture our products. We do, however, purchase some raw materials from single sources, but we believe that additional sources of supply are readily available. Further, to the extent additional sources of supply are not readily available, we believe that we could manufacture such raw materials.

We follow quality management procedures in accordance with applicable regulations and guidance for the development and manufacture of materials and device, biotechnology or combination products that support clinical trials and commercialization. In order to meet our customers' needs in this area, all of our manufacturing facilities in Eden Prairie, Minnesota and Ballinasloe, Ireland are certified to ISO 13485 and registered with the U.S. FDA as "Contract Manufacturers." In addition, one of our manufacturing facilities and our warehouse facility in Eden Prairie, Minnesota are certified to ISO 9001.

Government Regulation

OTHER FACTORS IMPACTING OUR OPERATIONS

Medical device and in vitro diagnostic products are required to undergo regulatory review processes that are governed by the FDA and other international regulatory authorities. The process of regulatory review and approval is often prolonged, expensive and uncertain. New medical devices can only be marketed in the U.S. after a pre-market notification for 510(k) clearance or a PMA by the FDA. These processes can take anywhere from several months (e.g., for medical device products seeking regulatory approval under the 510(k) clearance process) to several years (e.g., for medical device products seeking regulatory approval under the PMA application process). In the E.U., regulatory approval is signified by the CE Mark, which is generally granted by one of several competent authorities and is based on the submission of a design dossier, a manufacturer validation assessment, a third-party assessment, and review of the design dossier by a "Notified Body." In 2017, the E.U. authorized a new medical device regulation ("E.U. MDR"). E.U. MDR imposes significant additional pre-market and post-market requirements, became effective for devices submitted for CE Mark after May 2021. Medical devices granted CE Mark prior to May 2021 may continue to be sold until December 2027 for class III and class IIb devices and until December 2028 for class IIa and class I devices, or until the CE Mark expires, whichever comes first, provided they are actively transitioning to E.U. MDR with no significant changes to the design or intended use of the device.

For our customers' products that incorporate our performance coating and IVD technologies, the burden of securing regulatory approval typically rests with the customer, as the medical device manufacturer. For our vascular intervention products, the burden of securing regulatory approval rests on us, unless we contract with other organizations to pursue such approval.

In support of our customers' and our own regulatory filings, we maintain various confidential Device Master Files with the FDA and provide technical information to other regulatory agencies outside the U.S. regarding the nature, chemical structure and biocompatibility of our reagents. Our licensees generally do not have direct access to these files. However, they may, with our permission, reference these files in their various regulatory submissions to these agencies. This approach allows regulatory agencies to understand the details of our technologies without our having to share this highly confidential information with our customers.

U.S. legislation allows companies, prior to obtaining FDA clearance or approval to market a medical product in the U.S., to manufacture medical products in the U.S. and export them for sale in international markets. This generally allows us to realize earned royalties sooner and may result in opportunities to market our vascular intervention products in other countries. However, sales of medical products outside the U.S. are subject to international requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required by the FDA.

Human Capital

OTHER FACTORS IMPACTING OUR OPERATIONS

As of September 30, 2024, we had 389 employees, of which 97 were employed outside the U.S., primarily in manufacturing functions. We are not a party to any collective bargaining agreements.

Our success depends upon our ability to retain and attract highly qualified management and technical personnel. Talent management is critical to our ability to execute on our long-term growth strategy. Through our history of technological innovation, we appreciate the importance of retention, growth and development of our employees. We are committed to an inclusive culture which values equality, opportunity, and respect. In support of our inclusive culture, we believe we offer competitive compensation and benefits, including an annual pay gap assessment; provide respectful workplace training to strengthen employee understanding; and strive to recruit a diverse talent pool across all levels of the organization. We are focused on the engagement and empowerment of our employees through demonstration of our foundational values, which we refer to as the five Cs: we have *courage* to face challenges with determination, honesty and resourcefulness; *candor* to speak openly and respectfully; *collaboration* that recognizes teamwork as the key to success; *camaraderie* that is genuine and supportive; and *commitment* to our cause.

SEC FILINGS

We file annual reports, quarterly reports, proxy statements, and other documents with the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public may obtain any documents that we file with the SEC at <http://www.sec.gov>.

We make available, free of charge, copies of our annual report on Form 10-K, proxy statement, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act on our website, www.surmodics.com, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our website as a part of, or incorporating it by reference into, our Form 10-K.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

As of November 15, 2024, the names, ages and positions of the Company's executive officers were as follows:

Name	Age	Position
Gary R. Maharaj	61	President and Chief Executive Officer
Timothy J. Arens	57	Senior Vice President of Finance and Information Technology and Chief Financial Officer
Charles W. Olson	60	Senior Vice President and President, Medical Device Coatings
Teryl L.W. Sides	55	Senior Vice President and President, Vascular Interventions
Joseph J. Stich	59	Senior Vice President Human Resources and President, In Vitro Diagnostics
Gordon S. Weber	61	Senior Vice President of Legal, General Counsel and Secretary

Gary R. Maharaj joined the Company in December 2010 as President and Chief Executive Officer and was also appointed to the Surmodics Board of Directors at such time. Prior to joining Surmodics, Mr. Maharaj served as President and Chief Executive Officer of Arizant Inc., a provider of patient temperature management systems in hospital operating rooms, from 2006 to 2010. Previously, Mr. Maharaj served in several senior-level management positions for Augustine Medical, Inc. (predecessor to Arizant Inc.) from 1996 to 2006, including Vice President of Marketing, and Vice President of Research and Development. During his over 35 years in the medical device industry, Mr. Maharaj has also served in various management and research positions for the orthopedic implant and rehabilitation divisions of Smith & Nephew, PLC.

Timothy J. Arens joined the Company in February 2007 as Director, Business Development and became Senior Director of Financial Planning and Analysis and General Manager, In Vitro Diagnostics in October 2010. He was promoted to Vice President of Finance and Interim Chief Financial Officer in August 2011 and in February 2013 became Vice President Corporate Development and Strategy. In May 2018, Mr. Arens was named interim Vice President of Finance and Chief Financial Officer for a second time and in February 2019 he was named Vice President of Finance and Chief Financial Officer. In April 2020, he was promoted to Senior Vice President of Finance and Information Technology and Chief Financial Officer. Prior to joining Surmodics, Mr. Arens was employed at St. Jude Medical, Inc., a medical technology company, from 2003 to 2007, in positions of increasing responsibility related to business development and strategic planning functions.

Charles W. Olson joined the Company in July 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. In April 2005, the position of Vice President, Sales was added to his responsibilities. In November 2008, Mr. Olson was named Vice President of our Cardiovascular business unit, in October 2010, he was named Senior Vice President and General Manager, Medical Device, and in August 2016 he was named Senior Vice President of Commercial and Business Development, Medical Devices. In May 2022, Mr. Olson was named Senior Vice President and President, Medical Device Coatings. Prior to joining Surmodics, Mr. Olson was employed as General Manager at Minnesota Extrusion from 1998 to 2001 and at Lake Region Manufacturing in project management and technical sales from 1993 to 1998.

Teryl L.W. Sides joined the Company in November 2018 as Senior Vice President and Chief Marketing Officer. In April 2020, Ms. Sides was promoted to Senior Vice President of Product Development and Chief Marketing Officer. In May 2022, Ms. Sides was named Senior Vice President and President, Vascular Interventions. Before joining Surmodics, Ms. Sides served as Founder and Chief Executive Officer of Projectory, a consulting firm that provides strategic marketing services to medical technology clients, ranging from start-ups to global businesses, from 2011 to 2018. Prior to joining Projectory, Ms. Sides was the Vice President of Marketing and Product Development for Arizant, Inc. from 1998 to 2011.

Joseph J. Stich joined the Company in March 2010 as Vice President of Corporate Development and Strategy. In August 2011, Mr. Stich became Vice President, Business Operations and General Manager In Vitro Diagnostics. In September 2013, Mr. Stich's role was adjusted to Vice President and General Manager, In Vitro Diagnostics. In April 2020, Mr. Stich was promoted to Senior Vice President of Human Resources and General Manager, In Vitro Diagnostics. In May 2022, Mr. Stich was named Senior Vice President Human Resources and President, In Vitro Diagnostics. Prior to joining Surmodics, Mr. Stich was Vice President of Corporate Development for Abraxis BioScience, LLC, a biotechnology company focused on oncology therapeutics, from 2009 to 2010. Prior to joining Abraxis, he was a Vice President for MGI Pharma, Inc., a biopharmaceutical company, from 2005 to 2009. Mr. Stich's prior experience also includes serving as President/COO of Pharmaceutical Corp. of America (a subsidiary of Publicis Healthcare Specialty Group), and positions of increasing responsibility in sales and marketing at Sanofi-Aventis Pharmaceuticals.

Gordon S. Weber joined the Company in May 2020 as Senior Vice President of Legal, General Counsel and Secretary. Prior to joining Surmodics, Mr. Weber served as the Founder and President of Sapere Aude, LLC, a consulting firm, from 2018 to 2020. From 2017 to 2018, Mr. Weber served as Vice President, General Counsel and Secretary of CHF Solutions, Inc., which manufactures and markets ultrafiltration systems for patients suffering from fluid overload. Mr. Weber served as Vice President, General Counsel and Secretary of Vascular Solutions, Inc., a medical device company focused on products treating coronary and peripheral vascular disease, from 2013 until the company was acquired by Teleflex Incorporated in 2017. Mr. Weber practiced law for 13 years with Faegre & Benson LLP (now Faegre Drinker Biddle & Reath LLP), where he was Partner. Mr. Weber began his career with the accounting firm now known as KPMG and has served as Corporate Controller for Osmonics, Inc., an NYSE-listed manufacturer of fluid filtration equipment.

The executive officers of the Company are elected by and serve at the discretion of the Board of Directors. None of our executive officers are related to any other executive officer or any of our directors.

ITEM 1A. RISK FACTORS.

RISKS RELATING TO THE MERGER

The completion of the Merger is subject to a number of conditions, many of which are largely outside of the parties' control, and, if these conditions are not satisfied or waived on a timely basis, the Merger Agreement may be terminated and the Merger may not be completed.

The Merger is subject to various closing conditions that remain open, including:

- (1) the expiration or termination of the waiting period applicable to the consummation of the Merger under the HSR Act;
- (2) the absence of any judgment, ruling, order, writ, injunction or decree of any governmental authority, nor any statute, code, decree, law, healthcare law, act, ordinance, rule, regulation or order of any governmental authority or other legal restraint or prohibition, that is in effect that would make the Merger illegal or otherwise prevent or prohibit its consummation;
- (3) subject to specific standards, the accuracy of the representations and warranties of the other party or parties;
- (4) the performance or compliance in all material respects by the other party or parties of such party's or parties' covenants, obligations, and agreements under the Merger Agreement;
- (5) with respect to Parent's and Merger Sub's obligations to consummate the merger, the absence of a material adverse effect (as defined in the Merger Agreement) and the absence of any changes having occurred that would reasonably be expected to have, individually or in the aggregate, a material adverse effect;
- (6) our having delivered to Parent a certificate, dated as of the closing date and signed by one of our executive officers, certifying to the satisfaction of the foregoing conditions; and
- (7) Parent and Merger Sub having delivered to us a certificate, dated as of the closing date and signed by an executive officer, certifying to the satisfaction of the foregoing conditions.

The failure to satisfy all of the required conditions could delay the completion of the Merger by a significant period of time or prevent it from closing. Any delay in completing the Merger could cause the parties to not realize some or all of the benefits that are expected to be achieved if the Merger is successfully completed within the expected timeframe. There can be no assurance that the conditions to closing of the Merger will be satisfied or waived or that the Merger will be completed within the expected timeframe, or at all.

The Merger Agreement and the pendency or failure of the Merger could have a material adverse effect on our business, results of operations, financial condition and stock price.

There can be no assurance that the conditions to the closing of the Merger will be satisfied or waived or that the Merger will be completed in a timely manner, or at all. If the Merger is not completed within the expected timeframe or at all, our ongoing business, relationships and financial condition could be materially adversely affected and we will be subject to a variety of additional risks and possible consequences associated with the failure to complete the Merger, including the following:

- upon termination of the Merger Agreement under specified circumstances, we may be required to pay Parent a termination fee of \$20,380,000;
- we have incurred and will continue to incur substantial transaction costs, including legal, accounting, financial advisor, economic advisor, electronic discovery service, filing, printing and mailing fees, regardless of whether the Merger closes;
- under the Merger Agreement, we are subject to restrictions on the conduct of our business prior to the closing of the Merger, which may adversely affect our ability to execute our business strategies; and
- the Merger, whether or not it closes, has significantly diverted and will continue to significantly divert the attention of certain of our management and other key employees from ongoing business activities, including the pursuit of other opportunities that could be beneficial to us as an independent company.

If the Merger is not completed, these risks could materially affect our business and financial results, the trading price of our common stock, including to the extent that the market price of our common stock is positively affected by a market assumption that the Merger will be completed, and investor confidence in our business.

While the Merger is pending, we will be subject to several business uncertainties and contractual restrictions that could adversely affect our business and operations.

In connection with the pending Merger, some customers, vendors, distributors, suppliers, landlords, service providers or other third parties with which we have important business relationships may react unfavorably, including by delaying or deferring decisions concerning their business relationships or transactions with us, which could adversely affect our revenues, earnings, funds from operations, cash flows, expenses and prospects, regardless of whether the Merger is completed. In addition, due to restrictions in the Merger Agreement on the conduct of our business prior to completing the Merger, we are unable, without Parent's prior written consent, during the pendency of the Merger, to pursue strategic transactions, undertake significant capital projects, undertake certain significant financing transactions and otherwise pursue other actions, even if such actions would prove beneficial, and may cause us to forego certain opportunities we might otherwise wish to pursue. Parent may withhold its consent of these items for any reason. In addition, the pendency of the Merger may make it more difficult for us to effectively retain and incentivize key personnel and may cause distractions from our strategy and day-to-day operations and result in a decline in productivity for our current employees and management.

We have incurred and will continue to incur substantial transaction fees and costs in connection with the Merger that could adversely affect our business and operations if the Merger is not completed.

We have incurred and will incur significant non-recurring transaction fees, which include legal and advisory fees and substantial costs associated with completing the Merger, including costs related to the Second Request and any divestitures required to obtain regulatory approvals, and which could adversely affect our business operations and cash position if the Merger is not completed.

The termination fee and restrictions on solicitation contained in the Merger Agreement may discourage other companies from trying to acquire us while the Merger is pending.

The Merger Agreement prohibits us from soliciting, initiating, knowingly encouraging or knowingly facilitating any competing acquisition proposals, subject to certain limited exceptions. The Merger Agreement also contains certain termination rights, including, but not limited to, our right to terminate the Merger Agreement to accept a superior proposal (as defined in the Merger Agreement), subject to and in accordance with the terms and conditions of the Merger Agreement. The Merger Agreement further provides that, upon our termination of the Merger Agreement to enter into an alternative acquisition agreement that is the subject of a superior proposal, we will be required to pay Parent a termination fee of \$20,380,000 in cash. The termination fees and restrictions in the Merger Agreement relating to acquisition proposals by third parties, including with respect to the process such third parties would need to follow, could discourage other companies from trying to acquire us, even though those other companies might be willing to offer greater value to our shareholders than they will receive in the Merger.

Active or future litigation against us, Parent, or the members of their respective boards could prevent or delay the completion of the Merger or result in the payment of damages following completion of the Merger or otherwise negatively affect our business and operations.

In July 2024, two of our shareholders filed separate lawsuits in New York State court against us and our board (the "New York Lawsuits"). The New York Lawsuits allege that the proxy statement relating to the meeting at which the Merger was approved by our shareholders was materially misleading and contained material omissions in certain respects. The New York Lawsuits seek preliminary and permanent injunctive relief, rescission of the transaction or actual or punitive damages, and attorney's fees. No defendant has been served, and no additional proceedings have occurred in the New York Lawsuits. It is possible that the New York Lawsuits or other additional shareholder complaints, including securities-fraud class actions, demands for books and records, or other similar matters, may be filed by certain of our shareholders challenging the Merger. The outcome of such lawsuits cannot be assured, including the amount of costs associated with defending these claims or any other liabilities that may be incurred in connection with the litigation of these claims. If a plaintiff in any such lawsuits is successful in obtaining an injunction prohibiting the parties from completing the Merger, such injunction may delay the consummation of the Merger in the expected timeframe, or may prevent the Merger from being consummated at all. Whether or not any such plaintiff's claim is successful, this type of litigation can result in significant costs, including costs associated with the indemnification of obligations to our directors, and divert management's attention and resources from the closing of the Merger and ongoing business activities, which could adversely affect our business, results of operations and financial condition.

Uncertainty about the Merger has adversely impacted our ability to retain employees and may adversely affect the relationships between us and our customers, suppliers, distributors, business partners, vendors, landlords, service providers and other employees, whether or not the Merger is completed.

Since the announcement of the Merger, employees on our vascular intervention products direct sales and research and development teams, as well as on our financial reporting team, have terminated their employment with us, and reported to us that they did so in

part due to uncertainty related to the merger. The loss of employees from our direct sales team may prevent us from achieving our commercial objectives for our vascular intervention products in fiscal 2025 and beyond. Under the Merger Agreement, we may not hire employees, including replacement employees, above certain compensation levels without the consent of Parent. The replacement of several of the employees that have terminated their employment with us since the Merger requires the consent of Parent. In certain cases, Parent has declined to provide such consent, and it may deny future consent requests to replace employees.

The loss of employees from our vascular intervention research and development team may delay, or prevent us from completing, efficiently, or at all, products under development for our vascular intervention portfolio. The loss of certain employees may impair our ability to conduct our operations efficiently and effectively. Further, the loss of employees may have a cascading effect on our ability to retain other employees. Ongoing uncertainties related to the merger may continue to impair our ability to retain, recruit or motivate key management and technical, manufacturing, and other personnel.

In response to the announcement of the Merger, existing or prospective customers, suppliers, distributors, business partners, vendors, landlords, service providers and other of our third party relationships may delay, defer or cease providing goods or services or continuing work on strategic programs, delay or defer other decisions concerning our business, refuse to extend credit to us or extend the terms of material contracts, or otherwise seek to change the terms on which they do business with us. Any such delays or changes to terms could materially adversely harm our business.

If the Merger is not consummated by February 28, 2025 (which date may be extended one or more times, for up to nine additional months in total, under specified circumstances), either we or Parent may terminate the Merger Agreement, subject to certain exceptions. In the event the Merger Agreement is terminated by either party, we will have incurred significant costs and will have diverted significant management focus and resources from other strategic opportunities and ongoing business activities without realizing the anticipated benefits of the Merger, which could be materially adverse to us.

Actions of activist shareholders or other parties may impair our ability to consummate the Merger or otherwise negatively impact our business.

Actions taken by activist shareholders could impair our ability to satisfy conditions to the consummation of the Merger or otherwise preclude us from consummating the Merger. Activist shareholders could also take actions that disrupt our business, divert the time and attention of management and our employees away from our business operations, cause us to incur substantial additional expense, create perceived uncertainties among current and potential customers, clients, suppliers, employees and other constituencies as to our future direction as a consequence thereof, which may result in lost sales, impaired supplier relationships or other business arrangements and the loss of potential business opportunities, and make it more difficult to attract and retain qualified personnel and business partners.

The occurrence of any of these Merger-related events individually or in combination could materially and adversely affect our business, results of operations, financial condition and the market price of our common stock.

RISKS RELATING TO OUR BUSINESS, STRATEGY AND INDUSTRY

We had a net loss for our 2024 fiscal year, expect to incur net losses in the future, and may not be able return to or sustain profitability.

We incurred a net loss of \$(11.5) million in our fiscal year ended September 30, 2024 and expect to continue to have net losses in the future. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we continue our commercialization efforts to increase adoption of our products, expand existing relationships with our customers, pursue regulatory clearances or approvals for our planned or future products, conduct clinical trials and registry studies on our existing and planned or future products, and develop new products or add new features to our existing products. We expect to continue to incur losses in the future, which may fluctuate significantly from period to period. If our revenue declines or fails to grow at a rate faster than increases in our cost of goods sold and operating expenses, we will not be able to return to and maintain profitability in future periods. We cannot ensure that we will return to profitability or that, if we do become profitable, we will be able to sustain profitability.

Failure of our SurVeil DCB products to obtain a meaningful market share may limit our revenue and adversely impact our operating results, balance sheet, cash flows and liquidity.

In June 2023, our SurVeil DCB products received premarket approval from the U.S. Food and Drug Administration allowing the products to be marketed and sold in the U.S. by Abbott under our exclusive worldwide distribution agreement with them. In the first quarter of fiscal 2024, we completed shipment of Abbott's initial stocking order of commercial units of the SurVeil DCB products. Following the completion of the stocking order, we have continued to manufacture and ship commercial units of the products to Abbott. Upon our shipments of commercial units of the SurVeil DCB products, we recognized product sales revenue, which included both (i) the contractual transfer price, and (ii) an estimate of Surmodics' share of net profits resulting from product sales by Abbott to third parties.

As of September 30, 2024, contract asset balances associated with estimated *SurVeil* DCB profit-sharing expected to be collected from Abbott totaled \$2.0 million, which was reported in contract assets, current and other assets, noncurrent on the consolidated balance sheets. Based on profit sharing reports provided by Abbott, we estimate that less than 10% of the commercial units of the *SurVeil* DCB products that we shipped to Abbott in our fiscal 2024 were sold by Abbott prior to September 30, 2024. We will not collect any profit-sharing revenue on units of the *SurVeil* DCB product that Abbott does not sell prior to the expiration of the product, which is currently two years following production. If a substantial portion of the *SurVeil* DCB units that we have shipped to Abbott expire before Abbott sells them to third parties, it would result in a reduction of the contract asset that was previously recognized upon the shipment of those units sold to Abbott, which may have an adverse impact on our operating results, balance sheet, cash flows and liquidity.

DCBs are used to treat peripheral artery disease in the upper leg. The U.S. DCB market in which the *SurVeil* DCB product competes, is dominated by three companies. We estimate that those three companies have more than 90% of the market share. Further, we believe that products compatible with a 0.018 guidewire represent over 40% of that market, and that this segment of the market is growing at a substantially higher rate than products compatible with larger diameter guidewires. Our *SurVeil* DCB product is not compatible with a 0.018 guidewire. Based on forecasts for the *SurVeil* DCB product, received from Abbott, we expect to ship less than one-third of the *SurVeil* DCB units to Abbott in fiscal 2025 compared to the number of units that were shipped to Abbott in fiscal 2024. In the periods following the shipment of the initial *SurVeil* DCB product stocking order to Abbott, several factors including, low production volume, associated under-absorption and production inefficiencies, and the expiration of raw material inventory, have resulted in an unfavorable impact on the product gross profit margins of our medical device segment. If our *SurVeil* DCB product does not capture a meaningful share of the market in which it competes, and demand for the product is insufficient to permit us to produce it at an efficient scale, our revenue may be limited and our operating results, balance sheet, cash flows and liquidity may be adversely affected.

The loss of, or significant reduction in business from, one or more of our major customers could significantly reduce our revenue, earnings or other operating results.

A significant portion of our revenue is derived from a relatively small number of customers. Two of our customers combined provided approximately 28% of our revenue in fiscal 2024. Revenue from Abbott and Medtronic represented approximately 16% and 12%, respectively, of our total revenue for fiscal 2024 and was generated from multiple products and fields of use. The loss of Abbott, Medtronic, or any of our other large customers, or reductions in business from them, could have a material adverse effect on our business, financial condition, results of operations, and cash flow. There can be no assurance that revenue from any customer will continue at their historical levels. If we cannot broaden our customer base, we will continue to depend on a small number of customers for a significant portion of our revenue.

The long-term success of our business may suffer if we are unable to maintain and expand our licensing base, including with customers who may perceive our vascular intervention products as competing with their products.

We intend to continue pursuing a strategy of licensing our performance coating technologies that impart lubricity, pro-healing and biocompatibility characteristics, as well as drug-delivery capabilities (together, “performance coatings” or “performance coating technologies”) to a diverse array of medical device companies, thereby expanding the commercialization opportunities for our technologies. A significant portion of our revenue is derived from customer devices used in connection with procedures in neurovascular, peripheral vascular, cardiovascular, and structural heart and other applications. As a result, our business is susceptible to adverse trends in procedures. We may also be subject to adverse trends in specific markets such as the cardiovascular industry, including declines in procedures using our customers’ products as well as declines in average selling prices from which we earn royalties. Further, some of our performance coating technology customers may consider the vascular intervention products that we sell directly to healthcare providers to be competitive with their products.

Our success will depend, in part, on our ability to retain existing performance coating technology customers and to attract new licensees, to enter into agreements for additional applications with existing licensees, and to develop technologies for use in new applications. There can be no assurance that we will be able to identify, develop and adapt our technologies for new applications in a timely and cost-effective manner; that new license agreements will be executed on terms favorable to us; that new applications will be accepted by customers in our target markets; or that products incorporating newly licensed technology, including new applications, will gain regulatory approval, be commercialized or gain market acceptance. Delays or failures in these efforts could have an adverse effect on our business, financial condition and operating results. In addition, we cannot be sure that existing or potential customers will not avoid using our performance coating technologies because they perceive our vascular intervention products to be a competitive threat, which could have an adverse effect on our business, financial condition and operating results.

Our success depends on our ability to effectively develop and market our products against those of our competitors.

We operate in highly competitive and quickly evolving fields, and new developments are expected to continue at a rapid pace. Our success depends, in part, upon our ability to maintain competitive positions in the development of technologies and products in the fields of surface modification, device drug delivery, medical device products and diagnostics. Our performance coating technologies compete with technologies developed by a number of other companies. In addition, many medical device manufacturers have developed, are engaged in efforts to develop, or through common ownership are or may become affiliates of companies that have

developed, performance coating technologies for use on their own or affiliates' products, particularly in the area of drug delivery. With respect to commercialization of our vascular intervention medical device products, we have faced, and expect to continue to face, competitive pressures, including pricing pressure, from larger OEM suppliers, as well as larger medical device companies that produce similar products. Some of our existing and potential competitors (especially medical device manufacturers pursuing coating solutions through their own R&D efforts) have greater financial and technical resources, as well as production and marketing capabilities, than us. Further, even if we are successful in our plans to develop new medical device products, the commercialization of these products may be dependent upon a commercial partner to effectively market and sell our products to end users. Competitors may succeed in developing competing technologies or obtaining governmental approval for products before us. Products incorporating our competitors' technologies may gain market acceptance more rapidly than products using our technologies. Furthermore, there can be no assurance that new products or technologies developed by others, or the emergence of new industry standards, will not render our products or technologies or licensees' products incorporating our technologies noncompetitive or obsolete. Any new technologies that make our performance coatings, medical device platforms or In Vitro Diagnostics technologies less competitive or obsolete would have a material adverse effect on our business, financial condition and results of operations. Competition in the diagnostics market is highly fragmented, and in the product lines in which we compete, we face an array of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. Some of our competitors have substantially more capital resources, marketing experience, sales and R&D resources, and production facilities than we do.

We may not be successful in implementing our vascular intervention product development and commercialization strategy.

Since fiscal 2013, we have been focused on a key growth strategy to develop and commercialize vascular intervention products. To date, we have commercialized our vascular intervention products through collaborations with other medical device companies and through our own direct sales channel in the U.S. We may seek to expand the commercialization of these products through existing customers, third-party distributors, or other distribution channels.

Successfully implementing our vascular intervention product strategy places substantial demands on our resources and requires, among other things:

- maintenance and enhancement of our medical device R&D capabilities, including those needed to support the clinical evaluation and regulatory approval for our vascular intervention products;
- successful hiring, training, and retention of personnel;
- effective management of a business geographically located both in the U.S. and Ireland;
- effective commercialization of our products, including through strategic partnerships with our medical device customers, third-party distributors, and direct sales;
- efficient manufacture and procurement of complex products with demanding specifications;
- effective management of inventory levels to be able to meet anticipated customer demand, while mitigating the risk of excess or obsolete inventory;
- commitment from our medical device customers to market our products effectively or to devote resources necessary to provide effective sales;
- sufficient liquidity to support substantial investments in working capital, R&D, and selling, general and administrative ("SG&A") resources; and
- successful sales, marketing, field clinical support, and sales-related activities.

There is no assurance that we will be able to successfully implement our vascular intervention product strategy, which could lead to losses on the investments we are making in connection with this strategy, stranded assets, or asset write-downs, and may result in an adverse impact on our business, financial results and financial condition.

We anticipate that operating expenses related to the development and direct-sale commercialization of medical device products will have an adverse impact on our near-term operating results and financial position, and they may not be effective.

In fiscal 2022, we established a field sales team to sell our radial access and thrombectomy medical device products directly to healthcare providers in the U.S. Our SG&A expenses increased from \$30.7 million in fiscal 2021, the year before we established our medical device direct sales team, to \$56.8 million in fiscal 2024, with much of the increase due to personnel and other investments in our direct sales initiatives. We currently expect SG&A expenses to remain at their fiscal 2024 levels or higher.

Because we expect operating expenses related to our medical device products that we offer through direct sales to exceed the revenue from those products in fiscal 2025, we anticipate that such expenses will adversely impact our operating results and cash flow during the year, which is likely to have an adverse effect on our financial position. Accordingly, we may seek additional sources of funds,

including additional borrowing against our credit facility, to fund our continuing investment in the development and direct sale of our medical device products. Such funds may not be available on favorable terms, if at all.

In addition to the operating expenses associated with product development and direct-sale commercialization activities, such activities are subject to risks of failure that are inherent in the development and commercialization of new medical technologies or products and establishment of a new sales force. There can be no assurance that we will be successful in developing new technologies or products, or in commercializing any such technologies or products through direct sales, or otherwise. Even if we are successful in developing and commercializing new technologies or products, there can be no assurance that gross profits from their sales will exceed our operating expenses related to their development and commercialization.

Our credit agreement contains covenants that restrict our business and financing activities. All of our assets secure our obligations under the credit agreement and may be subject to foreclosure.

On October 14, 2022, we 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 (together “MidCap”). The MidCap Credit Agreement contains covenants that limit our ability to engage in certain transactions. Subject to limited exceptions, these covenants limit our 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 our 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 our capital stock;
- make certain investments, other than limited permitted acquisitions; and
- enter into transactions with our affiliates.

These provisions impose significant operating and financial restrictions on us and may limit our ability to compete effectively, take advantage of new business opportunities, or take other actions that may be in our, or our shareholders’, best interests.

In addition to the other covenants under the MidCap Credit Agreement, we must maintain minimum core net revenue levels tested quarterly if term loans exceed \$25.0 million.

The MidCap Credit Agreement contains customary indemnification obligations and customary events of default, including, among other things:

- non-payment;
- breach of warranty;
- non-performance of covenants and obligations;
- default on other indebtedness;
- certain judgments;
- change of control;
- bankruptcy and insolvency;
- impairment of security;
- regulatory matters; and
- material adverse effect.

Our obligations under the MidCap Credit Agreement are secured by all our existing and future acquired assets, including intellectual property and real estate.

Our inability to comply with any of the provisions of the MidCap Credit Agreement could result in a default under it. If such a default occurs, the lenders may elect to declare all borrowings outstanding, together with accrued interest and other fees, to be immediately due and payable, and it would have the right to terminate any commitments to provide further funds. If we are unable to repay outstanding borrowings when due, the lender also has the right under the MidCap Credit Agreement to proceed against the collateral granted to it to secure the indebtedness under the MidCap Credit Agreement. The occurrence of any of these events could have a material adverse effect on our business, financial condition, results of operations and liquidity.

We may seek to prepay our borrowings under the MidCap Credit Agreement before its maturity, which would subject us to early termination fees and may lead us to raise capital on unfavorable terms.

Subject to certain limitations, the term loans under our MidCap Credit Agreement have a prepayment fee for payments made prior to the maturity date equal to 1.0% of the prepaid principal amount. In addition, if the revolving credit facility under the MidCap Credit Agreement is terminated in whole or in part prior to the maturity date, we must pay a prepayment fee equal to 1.0% of the terminated

commitment amount. We also are required to pay a full exit fee at the time of maturity or full prepayment 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.

To obtain more favorable interest rates or credit terms, or for other financial or strategic reasons, we may seek to prepay our borrowings under the MidCap Credit Agreement. To do so, we may seek to raise additional capital through equity offerings or debt financings, and such additional financing may not be available to us on acceptable terms, or at all. Further, any additional equity or debt financing transaction may contain terms that are not favorable to us or our shareholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our shareholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. Further, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, and other operating restrictions that could adversely affect our ability to conduct our business.

If we enter into asset transactions, collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as the relinquishment or licensing of certain technologies or products that we otherwise might seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms.

Failure to successfully and profitably commercialize the Pounce™ venous thrombectomy product may limit our growth and adversely impact our operating results, balance sheet, cash flows and liquidity.

On July 2, 2021, we completed the acquisition of all outstanding shares of Vetex Medical Limited (“Vetex”). Vetex holds a U.S. Food and Drug Administration (“FDA” or the “Agency”) 510(k) clearance, E.U. CE Mark, and portfolio of patents related to the *Pounce* venous mechanical thrombectomy catheter product (the “*Pounce* Venous Thrombectomy System”). However, Vetex had not initiated commercial production or established commercialization of the product prior to the acquisition. We acquired Vetex with an upfront cash payment of \$39.9 million, a \$1.8 million cash payment made in the fourth quarter of fiscal 2024, and a \$1.8 million cash payment that is due in the fourth quarter of fiscal 2027. An additional \$3.5 million in payments are contingent upon the achievement of certain product development and regulatory milestones within a contingency period ending in fiscal 2027. As of the acquisition date, we recognized \$28 million in intangible assets, \$3 million in deferred tax liabilities and \$19 million in goodwill related to the acquisition.

We commercially launched the *Pounce* Venous Thrombectomy System in the second quarter of fiscal 2024. If potential customers do not adopt the *Pounce* Venous Thrombectomy System at sufficient levels to make it a commercial success, our operating results, cash flows and liquidity may be adversely impacted. Further, the goodwill and intangible assets that we recognized related to the acquisition may become impaired if the financial performance of the *Pounce* Venous Thrombectomy System does not meet our expectations, which could negatively affect our financial condition, operating results and cash flows.

Our failure to enhance our management systems and controls to support our expanded operations could seriously harm our operating results and business.

Implementation of our business strategy to expand our operations has placed significant demands on management and our administrative, development, operational, information technology, manufacturing, financial and personnel resources. Accordingly, our future operating results will depend on the ability of our officers and other key employees to continue to implement and improve our operational, development, customer support and financial control systems, and effectively train and manage our employee base. Otherwise, we may not be able to manage our expanded operations successfully.

Goodwill or other assets on our balance sheet may become impaired or require valuation reserves, which could have a material adverse effect on our operating results.

As of September 30, 2024, we had \$68.2 million of goodwill and intangible assets on our consolidated balance sheet. As required by the accounting guidance, we evaluate at least annually the potential impairment of our goodwill. Testing for impairment of goodwill involves the determination of the fair value of our reporting units. The estimation of fair values involves a high degree of judgment and subjectivity in the assumptions used. We also evaluate other assets on our balance sheet, including definite-lived intangible assets, whenever events or changes in circumstances indicate that their carrying value may not be recoverable. Our estimate of the fair value of the assets may be based on fair value appraisals or discounted cash flow models using various inputs. Future impairment charges could materially adversely affect our results of operations.

Our business could be adversely affected by global economic conditions.

Prolonged economic uncertainties or downturns could adversely affect our business, financial condition, and results of operations. Negative conditions in the general economy in either the U.S. or abroad, including conditions resulting from financial and credit market

fluctuations, increased inflation and interest rates, changes in economic policy, trade uncertainty, including changes in tariffs, sanctions, international treaties, and other trade restrictions, the occurrence of a natural disaster or global public health crisis, or armed conflicts, such as between Russia and Ukraine or between Israel and Hamas, impact corporate spending in general and negatively affect the growth of our business.

These conditions could make it difficult for us and our customers to forecast and plan future business activities accurately and could cause our customers to reevaluate or delay their decisions to license our technologies, purchase our products, or enter into R&D arrangements with us. A substantial downturn affecting our customers may cause them to react to worsening conditions by reducing their capital expenditures in general or by specifically reducing their spending on medical devices and technologies. We cannot predict the timing, strength, or duration of any economic slowdown, downturn, instability, or recovery, generally or within any particular industry or geography. Any downturn of the general economy or industries in which we operate would adversely affect our business, financial condition, and results of operations.

We recognize revenue in accordance with complex accounting standards, and changes in estimates, circumstances, or interpretations of standards may lead to accounting adjustments. Failure to implement these standards properly might impact the effectiveness of our internal control over financial reporting or impact the reliability of our financial reporting.

Our revenue recognition policies involve application of complex accounting standards, including the determination of when control is transferred to the customer, identification of performance obligations and determination of when they are satisfied, and estimates of variable consideration. Our compliance with such accounting standards often involves management's judgment regarding whether the criteria set forth in the standards have been met such that we can recognize as revenue the amounts that we expect to receive as payment for our products or services. We base our judgments on assumptions that we believe to be reasonable under the circumstances. However, these judgments, or the assumptions underlying them, may change over time. In addition, the SEC or the Financial Accounting Standards Board ("FASB") may issue new positions or revised guidance on the treatment of complex accounting matters. Changes in circumstances or third-party guidance could cause our judgments to change with respect to our interpretations of these complex standards, and transactions recorded, including revenue recognized, for one or more prior reporting periods, could be adversely affected. Further, failure to implement these standards properly could impact the effectiveness of our internal control over financial reporting or impact the reliability of our financial reporting, which could cause investors to lose confidence in our reported financial information and have a negative effect on the trading price of our stock.

In addition, based on the net profit-sharing provisions of the Abbott Agreement, the amount of revenue that we recognize on our sales of *SurVeil* DCB products to Abbott represents variable consideration and requires us to estimate Abbott's future net sales of those products during the period in which those products are shipped to Abbott. Abbott has discretion over setting its pricing structure for the products and has limited history of selling them. We, therefore, have limited information upon which to base our estimates of Abbott's net sales of *SurVeil* DCB products. We are required to refine our estimates of variable consideration for profit-sharing each quarter based on available information, which may result in adjustments to product revenue that may have been recognized in prior periods, which may have a material adverse impact on our results of operations.

The transfer price to Abbott of our SurVeil DCB products is denominated in Euros, which, together with our foreign operations, exposes us to certain risks related to fluctuations in U.S. dollar and foreign currency exchange rates.

The transfer price to Abbott for our *SurVeil* DCB products is denominated in Euros, while profit-sharing with Abbott on its sales of those products in the U.S. is denominated in U.S. dollars. In addition, our operations in Ireland conduct business in Euros. We report our consolidated financial statements in U.S. dollars. In a period where the U.S. dollar is strengthening or weakening relative to the Euro, our revenue and expenses denominated in the Euro are translated into U.S. dollars at a lower or higher value, respectively, than they would be in an otherwise constant currency exchange rate environment. We are also exposed to foreign exchange gains and losses on the Euro-denominated accounts receivable from Abbott and Euro-denominated cash balances held in the U.S. As our sales of *SurVeil* DCB products to Abbott and our foreign operations expand, the effects may become material to our consolidated financial statements.

Changes in product mix, increased manufacturing costs, and other factors could cause our product gross margin percentage to fluctuate or decline in the future.

Changes in our product mix and increased manufacturing costs could cause our product gross margin percentage (defined as product gross profit, or product sales less product costs, as a percentage of product sales) to fluctuate or decline in the future. These factors, together with the scale-up of our vascular intervention manufacturing operations with low and intermittent production volumes relative to manufacturing capacity, finite shelf life products, difficulty in forecasting demand for newly launched products, as well as related inefficiencies, adversely affected our product gross margin percentage for the last fiscal year, and these factors will likely continue to affect our product gross margin percentage in fiscal 2025 and beyond.

RISKS RELATING TO OUR OPERATIONS AND RELIANCE ON THIRD PARTIES

We rely on third parties to market, distribute and sell most products incorporating our coating and device technologies.

A principal element of our business strategy is to enter into licensing arrangements with medical device and other companies that manufacture products incorporating our technologies. We derived 34%, 47%, and 36% of our revenue from royalties and license fees (including related to our *SurVeil* DCB) under such licensing arrangements in fiscal 2024, 2023 and 2022, respectively. The revenue that we derive from such arrangements depends upon our ability, or our licensees' ability, to successfully develop, obtain regulatory approval for, manufacture (if applicable), market, and sell products incorporating our technologies. Many of these factors are outside of our control. Our failure, or the failure of our licensees, to meet these requirements could have a material adverse effect on our business, financial condition and results of operations.

Additionally, a licensee could modify its product in such a way that it no longer incorporates our technology. Moreover, under our standard license agreements, licensees can terminate the license for any reason upon 90 days' prior written notice. Existing and potential licensees have no obligation to deal exclusively with us and may pursue parallel development or licensing of competing technologies on their own or with third parties. A decision by a licensee to terminate its relationship with us could have a material adverse effect on our business, financial condition and results of operations.

A portion of our IVD business relies on distribution agreements and relationships with various third parties, and any adverse change in those relationships could result in a loss of revenue and harm that business.

We sell many of our IVD products outside of the U.S. through distributors. Some of our distributors also sell our competitors' products. If they favor our competitors' products for any reason, they may fail to market our products as effectively or to devote resources necessary to provide significant sales, which would cause our results to suffer. Additionally, we serve as the exclusive distributor in the U.S., Canada and Puerto Rico for DIARECT GmbH (Part of BBI Solutions) for its recombinant and native antigens. The success of these arrangements with these third parties depends, in part, on the continued adherence to the terms of our agreements with them. Any disruption in these arrangements could adversely affect our financial condition and results of operations.

We rely on our customers and business partners to accurately report and make payments under our agreements with them.

We rely on our performance coating technology customers to determine whether the products that they sell are royalty-bearing and, if so, to report and pay the amount of royalties owed to us under our agreements with them. The majority of our performance coatings technology license agreements with our customers give us the right to audit their records to verify the accuracy of their reports to us. However, these audits can be expensive, time-consuming and possibly detrimental to our ongoing business relationships with our customers. Inaccuracies in customer royalty reports have resulted in, and could result in, additional overpayments or underpayments of royalties, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the net profit-sharing provisions of the Abbott Agreement require Abbott to calculate, in accordance with the terms of the agreement, and report to us its net profits on its sales of our *SurVeil* DCB. Abbott is further obligated to make payments to us based on such net profits. The Abbott Agreement gives us the right to designate and pay for an independent auditor to audit the books and records of Abbott to verify the accuracy of its profit-sharing reports to us. However, such audits can be expensive and time-consuming. Inaccuracies in profit-sharing reports from Abbott could result in underpayments of profit-sharing by Abbott, which could have a material adverse effect on our business, financial condition and results of operations.

We currently have limited or no redundancy for the production of many of our products and their components, and we may lose revenue and be unable to maintain our customer relationships if we lose our production capacity.

We manufacture all of our performance coating reagents (and provide coating manufacturing services for certain customers) and our IVD products at one of our Eden Prairie, Minnesota facilities. We manufacture balloon catheter products and certain radial access device products at our facility in Ballinasloe, Ireland. We manufacture the *SurVeil* DCB and thrombectomy devices in one of our facilities in Eden Prairie, Minnesota. In addition, we rely upon sole-source suppliers for certain components and finished medical device products. If our existing production facilities or sole-source suppliers become incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our customers, including certain of our licensees. In addition, because most of our customers use our performance coating reagents to manufacture their own products that generate royalties and license fee revenue for us, failure by us to supply these reagents could result in decreased royalties and license fee revenue, as well as decreased revenue from our performance coating product sales. Without our existing production facilities, we would have no other means of manufacturing products until we were able to restore the manufacturing capability at these facilities or develop one or more alternative manufacturing facilities. Although we carry business interruption insurance to cover lost revenue and profits in an amount we consider adequate, this insurance does not cover all possible situations. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing customers resulting from our inability to produce products for them.

We may face product liability claims related to participation in clinical trials or the use or misuse of our products.

The development and sale of medical devices and component products involves inherent risks of product liability claims. For medical device products that incorporate our performance coating technologies, most of the licenses provide us with indemnification against such claims. However, there can be no assurance that product liability claims will not be filed against us for such products, or for

medical device products that we manufacture as part of our vascular intervention product strategy, that parties indemnifying us will have the financial ability to honor their indemnification obligations, or that such manufacturers will not seek indemnification or other relief from us for any such claims. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time, attention and resources. We have obtained a level of liability insurance coverage that we believe is appropriate to our activities, however, we cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any recall of products or devices incorporating our technologies because of alleged defects, whether such recall is instituted by us, by a customer, or is required by a regulatory agency. A product liability claim, recall or other claim with respect to uninsured liabilities, or for amounts in excess of insured liabilities, could have a material adverse effect on our business, financial condition and results of operations.

Our revenue will be harmed if we experience disruptions in our supply chain.

Supply chains across many industries have experienced delays and disruptions due to a wide variety of factors including labor and materials shortages and a lack of transportation capacity. A disruption in the supply of even a minor component of a product can have a major impact on the production and delivery of that product. If any of our suppliers becomes unwilling to supply components to us, experiences an interruption in its production, or is otherwise unable to provide us, on a timely basis or at all, with sufficient material to manufacture our reagents and other products, we will experience production interruptions. Further, we currently purchase some of the components we use to manufacture reagents from sole suppliers. If we lose our sole supplier of any particular reagent component or are otherwise unable to procure all components required for our reagent manufacturing for an extended period of time, we may lose the ability to manufacture the reagents our customers require to commercialize products incorporating our technology. This could result in lost royalties and license fees and product sales, which would harm our financial results. Adding suppliers to our approved vendor list may require significant time and resources. We routinely attempt to maintain multiple suppliers of each of our significant materials, so we will have alternative suppliers, if necessary. However, if the number of suppliers of a material is reduced, or if we are otherwise unable to obtain our material requirements on a timely basis and on favorable terms, our operations may be harmed.

We depend upon key personnel and may not be able to attract or retain qualified personnel in the future.

Our success depends upon our ability to retain and attract highly qualified management and technical personnel. We face intense competition for such qualified personnel. We do not maintain key person insurance, and we generally do not enter into employment agreements, except with certain executive officers. The loss of the services of one or more key employees or the failure to attract and retain additional qualified personnel could have a material adverse effect on our business, financial condition and results of operations.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

We collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees, on our networks. The secure maintenance of this information is critical to our operations and business strategy, and our customers expect that we will securely maintain their information. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers resulting from employee error, malfeasance or other disruptions. Any information technology breach could compromise our networks and the information stored on them could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under personal privacy laws and regulatory penalties, disrupt our operations and the services that we provide to our customers, damage our reputation and cause a loss of confidence in our products and services, any of which could adversely affect our business and competitive position.

Our information systems, and those of third-party suppliers with whom we contract, require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information technology, evolving systems and regulatory standards, and changing threats. These systems could be vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. We also are subject to other cyber-attacks, including state-sponsored cyber-attacks, industrial espionage, insider threats, computer denial-of-service attacks, computer viruses, ransomware and other malware, payment fraud or other cyber incidents. Any significant breakdown, intrusion, breach, interruption, corruption or destruction of these systems could have a material adverse effect on our business and reputation and could materially adversely affect our results of operations and financial condition.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

We may not be able to obtain, maintain or protect proprietary rights necessary for the commercialization of our technologies.

Our success depends, in large part, on our ability to obtain and maintain patents and trade secrets. We have been granted U.S. and foreign patents and have U.S. and foreign patent applications pending related to our proprietary technologies. There can be no

assurance that any pending patent application will be approved, that we will develop additional proprietary technologies that are patentable, that any patents issued will provide us with competitive advantages or will not be challenged or invalidated by third parties, that the patents of others will not prevent the commercialization of products incorporating our technologies, or that others will not independently develop similar technologies or design around our patents. Furthermore, because we generate a significant amount of our revenue through licensing arrangements, the loss or expiration of patent protection for our licensed technologies will result in a reduction of the revenue derived from these arrangements, which may have a material adverse effect on our business, cash flow, results of operations, financial position and prospects.

We may become involved in expensive and unpredictable patent litigation or other intellectual property proceedings which could result in liability for damages or impair our development and commercialization efforts.

Our commercial success also depends, in part, on our ability to avoid infringing patent or other intellectual property rights of third parties. There has been substantial litigation regarding patent and other intellectual property rights in the medical device and pharmaceutical industries, and intellectual property litigation may be used against us as a means of gaining a competitive advantage. Intellectual property litigation is complex, time consuming and expensive, and the outcome of such litigation is difficult to predict. If we were found to be infringing any third-party patent or other intellectual property right, we could be required to pay significant damages, alter our products or processes, obtain licenses from others, which we may not be able to do on commercially reasonable terms, if at all, or cease commercialization of our products and processes. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

Patent litigation or certain other administrative proceedings may also be necessary to enforce our patents or to determine the scope and validity of third-party proprietary rights. These activities could result in substantial cost to us, even if the eventual outcome is favorable to us. An adverse outcome from any such litigation or interference proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using our technology. Any action to defend or prosecute intellectual property would be costly and result in significant diversion of the efforts of our management and technical personnel, regardless of outcome, and could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through trade secret or confidentiality agreements with our employees, consultants, potential licensees, or other parties as well as through other security measures. There can be no assurance that these agreements or any security measure will provide meaningful protection for our un-patented proprietary information. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we determine that our proprietary rights have been misappropriated, we may seek to enforce our rights which would draw upon our financial resources and divert the time and efforts of our management, and could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to convince our customers to adopt our advanced generation of hydrophilic coating technologies, our royalties and license fee revenue may decrease, and the expiration of the patent family protecting this technology has and will continue to result in a reduction of the royalties and license fee revenue associated with existing license agreements.

In our Medical Device segment, we have licensed our *PhotoLink* hydrophilic technology to a number of our customers for use in a variety of medical device surface applications. We have several U.S. and international issued patents and pending U.S. and international patent applications protecting various aspects of these technologies, including compositions, methods of manufacture, and methods of coating devices. The anticipated expiration dates of the patents range from fiscal 2025 to 2042. These patents and patent applications represent distinct families, with each family generally covering a successive generation of the technology, including improvements that enhance coating performance, manufacturability, or other important features desired by our customers.

Our fourth-generation *PhotoLink* technology was protected by a family of patents that expired in the first quarter of fiscal 2020 in all countries where patent coverage existed for the technology, except in Japan, where the relevant patent expired in the first quarter of fiscal 2021. Of the license agreements using our fourth-generation technologies, most continue to generate royalties and license fee revenue beyond patent expiration, but at a reduced royalty rate.

While we are actively working to encourage and support our customers' adoption of our advanced generations of our hydrophilic coating technology, there can be no assurance that they will do so, or that those customers that have adopted, or will adopt, our hydrophilic coating technology will sell products utilizing our technology which will generate earned royalties and license fee revenue for us.

If we or any of our licensees breach any of the agreements under which we have in-licensed intellectual property from others, we could be deprived of important intellectual property rights and future revenue.

We are a party to various agreements through which we have in-licensed or otherwise acquired rights to certain technologies that are important to our business. In exchange for the rights granted to us under these agreements, we have agreed to meet certain research, development, commercialization, sublicensing, royalty, indemnification, insurance or other obligations. If we or one of our licensees fails to comply with these obligations set forth in the relevant agreement through which we have acquired rights, we may be unable to effectively use, license, or otherwise exploit the relevant intellectual property rights and may be deprived of current or future revenue that is associated with such intellectual property.

RISKS RELATING TO CLINICAL AND REGULATORY MATTERS

The development of new products and enhancement of existing products requires significant research and development and regulatory approvals, which may require clinical trials, all of which may be very expensive and time-consuming and may not result in commercially viable products.

The development of new products and enhancement of existing products requires significant investment in research and development and regulatory approvals. Regulators may require successful clinical trials prior to granting approvals for new or enhanced products. All of these requirements can be very expensive and time-consuming.

There can be no assurance that any products now in development, or that we may seek to develop or refine in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to obtain regulatory approval for new products or enhanced products, our ability to successfully compete in the markets in which we participate may be materially adversely impacted. A delay in the development or approval of new products and technologies may also adversely impact the timing of when these products contribute to our future revenue and earnings growth.

We cannot be sure that clinical studies of our products will be successful, or that their results will be adequate to obtain or maintain regulatory approvals.

We cannot be sure that the endpoints or safety profile of any clinical study will be met. In addition, we cannot be sure that any clinical study that is successful will support any regulatory objective related to the study. We may expend significant financial and human capital resources on clinical studies. If they fail to achieve their objectives, it could have a material adverse effect on our business, financial condition and results of operations.

Healthcare policy changes may have a material adverse effect on us.

Healthcare costs have risen significantly during the past decade. There have been and continue to be proposals by legislators, regulators and third-party payers to reduce healthcare expenditures. Certain proposals, if implemented, would impose limitations on the prices our customers will be able to charge for our products, or the amounts of reimbursement available for their products from governmental agencies or third-party payers, or otherwise negatively impact pricing and reimbursement. Because a significant portion of our revenue is currently derived from royalties on products that constitute a percentage of our customer's product's selling price, these limitations could have an adverse effect on our revenue.

Healthcare reform continues to be a prominent political topic. We cannot predict what healthcare programs and regulations may ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the U.S. or internationally may have on our business.

Vascular intervention medical devices and other products incorporating our technologies are subject to increasing scrutiny and regulations, including extensive approval/clearance processes and manufacturing requirements. Any adverse regulatory and/or enforcement action (for us or our licensees) may materially affect our financial condition and business operations.

Our products and our business activities are subject to complex regulatory regimes both in the U.S. and internationally. Additionally, certain state governments and the federal government have enacted legislation aimed at increasing transparency of industry interactions with healthcare providers. Any failure to comply with these legal and regulatory requirements could impact our business. In addition, we will continue to devote substantial human capital and financial resources to further developing and implementing policies, systems and processes to comply with enhanced legal and regulatory requirements, which may impact our business and results of operations. We anticipate that governmental authorities will continue to scrutinize our industry closely, and that additional regulation may increase compliance and legal costs, exposure to litigation, and other adverse effects to our operations.

To varying degrees, the FDA and comparable agencies outside the U.S. require us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our products. Our compliance with these laws and regulations takes significant human capital and financial resources; involves stringent testing and surveillance; involves attention to any needed product improvements (such as modifications, repairs, or replacements); and may include significant limitations of the uses of our products.

Changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of products incorporating our technologies or subject us to additional regulation. Failure or delay by us or our licensees in obtaining FDA, E.U., and other necessary regulatory approval or clearance, or the loss of previously obtained approvals, could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR SECURITIES

Our stock price has been volatile and may continue to be volatile.

The trading price of our common stock has been, and may continue to be, highly volatile, in large part attributable to developments and circumstances related to factors identified in “Forward-looking Statements” and “Risk Factors.” Our common stock price may rise or fall sharply at any time based on announcement regarding regulatory actions, our operations or our financial performance; as a result of sales executed by significant holders of our stock; because of short positions taken by investors from time to time in our stock; or due to factors unrelated to our performance, including industry-specific or general economic conditions. In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition and reputation. These factors may materially and adversely affect the market price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

Risk Management and Strategy

Surmodics has adopted the National Institute of Standards and Technology (“NIST”) Cybersecurity Framework as the basis for our approach to assessing, identifying, and managing material risks from cybersecurity threats. Using a nationally recognized vendor partner, we conduct yearly cybersecurity assessments (including policy and procedures) and penetration testing based on the NIST Cybersecurity Framework and principles. From the assessment results, we create a roadmap and prioritize it to address any noted deficiencies with our identification, protection, detection, response and recovery functions. This roadmap is used as a basis for our yearly cybersecurity planning initiatives to continually improve our systems, tools, architecture, training campaigns, monitoring and policies.

Also using a nationally recognized vendor partner, we have continuous (24x7x365) monitoring of our cloud solutions, perimeter and internal networks in addition to sharing of threat intelligence and remediation steps. Threat intelligence is evaluated, prioritized, and remediated on a continual basis throughout the year.

With the help and guidance of a vendor partner, we conduct quarterly end-user training campaigns designed to educate our end-user community on the social engineering methods used by sources of cybersecurity threats. In addition, monthly security updates are provided to the end-user community with information on current threats and general cybersecurity information.

On an annual basis, we collaborate with the third-party consulting firm that performs internal audit services for us to conduct a risk assessment of information systems controls for managing changes, operations, security and system development life cycles. In addition, we review System and Organization Controls (“SOC”) 1 or SOC 1 Type 2 reports for third-party service providers deemed significant to our environment. We perform the risk assessment and review of service providers in connection with Management’s annual assessments of the effectiveness of internal control over financial reporting. They serve as the basis for developing an internal audit plan to test information systems controls as they relate to the effectiveness of internal control over financial reporting. The results of the internal audit conducted under that audit plan are reviewed by the Audit Committee of the Board of Directors (the “Audit Committee”).

For any vendors providing or supporting critical business information systems, we require confidentiality provisions as part of a services agreement defining our business relationship and our requirements for protecting our data.

We maintain a security incident response plan that designates an incident response team comprised of information technology leadership and cybersecurity personnel as well as relevant third-party service providers. The objective of the plan is to provide for the timely diagnosis and mitigation of cyber events. The incident response team, in conjunction with the Company’s legal counsel, is responsible for determining whether a cybersecurity incident is material and requires reporting to our cyber insurance carrier and/or reporting pursuant to the disclosure requirement of the SEC.

To date of this Annual Report on Form 10-K, to the actual knowledge of the executive officers of the Company, no risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect the Company. However, we are subject to ongoing risks from cybersecurity threats that could materially affect us, including our business and reputation, as further described in Part I, Item 1A, "Risk Factors" of this Annual Report on Form 10-K.

Governance

Our Board of Directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

The Senior Director of Information Technology, in collaboration with our Cybersecurity Analyst, is responsible for setting the strategic direction and priorities for information security, coordination of enterprise-wide compliance with information security policies and procedures, as well as day-to-day information security management. The Cybersecurity Analyst role reports directly to the Senior Director of Information Technology. The Senior Director of Information Technology has a 34 years of information technology experience, including with cyber threats.

As necessary, but not less than once per year, the Senior Director of Information Technology makes a presentation on cyber threats and the Company's efforts to mitigate them to the Company's Chief Executive Officer, Chief Financial Officer, and the Audit Committee. In addition, the results of annual internal audits of the effectiveness of internal control over financial reporting, including relevant information systems, are reviewed by the Audit Committee.

ITEM 2. PROPERTIES.

Our principal operations are located in Eden Prairie, a suburb of Minneapolis, Minnesota, where we own a building that has approximately 64,000 square feet of space utilized by our Corporate, Medical Device and IVD reportable segments. We also own a 45,000 square foot building in Ballinasloe, Ireland dedicated to our Medical Device segment. We lease a warehouse in Eden Prairie through December 2025. We lease a 90,000 square foot facility in Eden Prairie through April 2028, which is primarily used by our Medical Device segment for operations, R&D, and manufacturing. We own an undeveloped parcel of land adjacent to our principal facility in Eden Prairie, which we may use to accommodate our growth needs. The MidCap Credit Agreement requires that all of our owned real property, including the properties set forth above, be subject to mortgages securing our obligations under the MidCap Credit Agreement.

ITEM 3. LEGAL PROCEEDINGS.

See the discussion of "Litigation" in Note 2 to the consolidated financial statements in "Financial Statements and Supplementary Data" in Part II, Item 8 of this Annual Report on Form 10-K, which is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES.

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our stock is traded on the Nasdaq Global Select Market under the symbol "SRDX."

Our transfer agent is:

Broadridge Corporate Issuer Solutions, Inc.
P.O. Box 1342
Brentwood, NY 11717
1-877-830-4936

According to the records of our transfer agent, as of November 15, 2024, there were 237 holders of record of our common stock.

We have never declared or paid any dividends on our common stock. We currently intend to retain future earnings, if any, for the operation and expansion of our business and to repurchase shares of our common stock under the repurchase authorization described below, if appropriate, and therefore we do not anticipate declaring or paying cash dividends in the foreseeable future. The declaration and payment by Surmodics of future dividends, if any, on our common stock will be at the sole discretion of the Board of Directors and will depend on our anticipated earnings, financial condition, capital requirements and other factors that the Board of Directors deems relevant. In addition, the Merger Agreement and the MidCap Credit Agreement both restrict our ability to pay dividends.

On November 6, 2015, the Company's Board of Directors authorized it to repurchase up to an additional \$20.0 million ("fiscal 2016 authorization") of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase ("ASR") transactions, tender offers or by any combination of such methods. The share repurchase program does not have a fixed expiration date.

On November 5, 2014, the Company's Board of Directors authorized it to repurchase up to \$30.0 million ("fiscal 2015 authorization") of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, ASR transactions, tender offers or by any combination of such methods. An aggregate of \$20.0 million of the fiscal 2015 authorization was utilized in fiscal 2015, with an additional \$4.7 million utilized in fiscal 2017. The share repurchase program does not have a fixed expiration date.

The Company has an aggregate of \$25.3 million available for future common stock purchases under the current authorizations. Both the Merger Agreement and the MidCap Credit Agreement restrict our ability to purchase our common stock.

Issuer Repurchases of Equity Securities

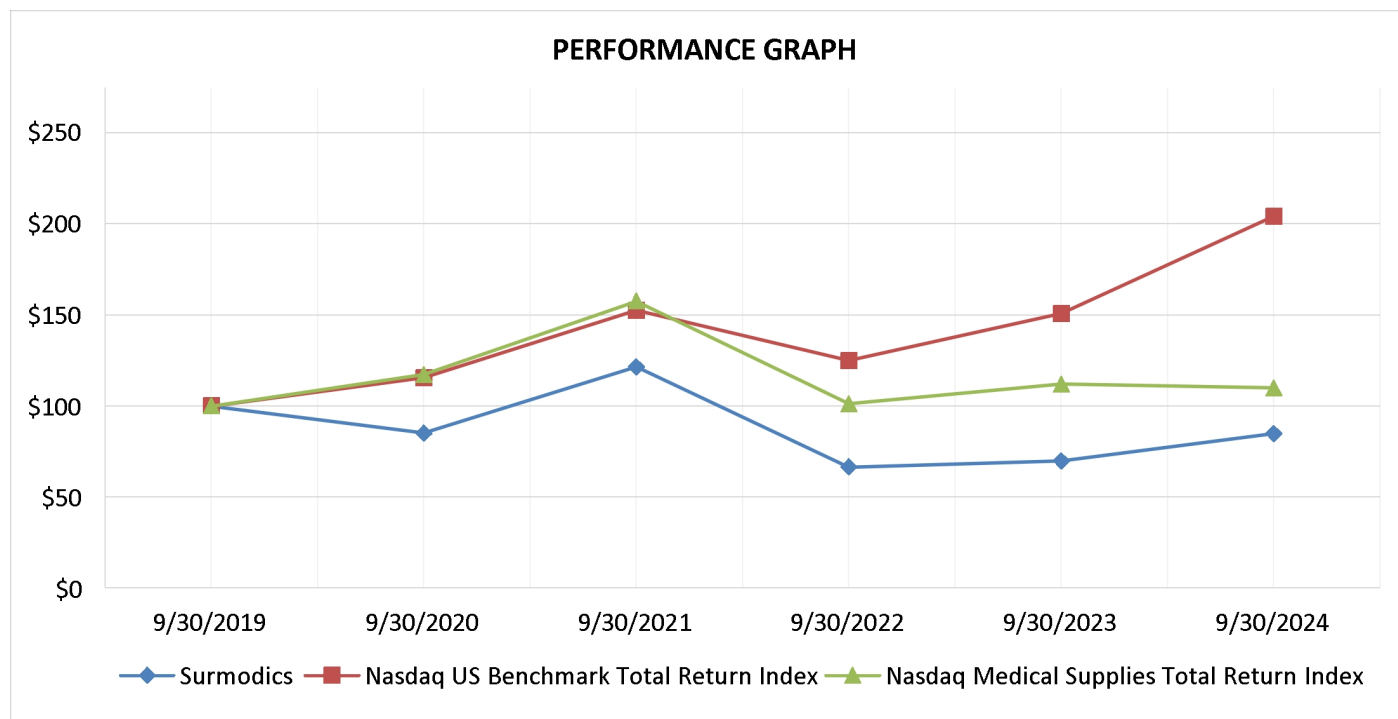
The following table presents the information with respect to purchases made by or on behalf of Surmodics, Inc. or any "affiliated purchaser" (as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934), of our common stock during the fourth quarter of fiscal 2024:

Period:	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
July 1 – 31, 2024	182	\$ 41.51	—	\$ 25,300,000
August 1 – 31, 2024	524	41.24	—	25,300,000
September 1 – 30, 2024	160	39.26	—	25,300,000
Total	<u>866</u>	<u>40.93</u>	<u>—</u>	

(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.

Stock Performance Chart

The following chart compares the cumulative total shareholder return on the Company's Common Stock with the cumulative total return on the Nasdaq US Benchmark Total Return Index (our broad equity market index) and the Nasdaq Medical Supplies Total Return Index (our published industry index). The comparisons assume \$100 was invested on September 30, 2019 and assume reinvestment of dividends.



<u>\$100 investment in stock or index</u>	<u>Ticker</u>	<u>9/30/2019</u>	<u>9/30/2020</u>	<u>9/30/2021</u>	<u>9/30/2022</u>	<u>9/30/2023</u>	<u>9/30/2024</u>
Surmodics	SRDX	\$ 100.00	\$ 85.07	\$ 121.56	\$ 66.46	\$ 69.85	\$ 84.78
Nasdaq US Benchmark Total Return Index	NQUSBT	100.00	115.46	152.43	124.98	150.66	204.31
Nasdaq Medical Supplies Total Return Index	NQUSB20102015T	100.00	117.23	157.58	101.10	112.10	110.02

ITEM 6. [RESERVED].

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis provide information management believes is useful in understanding the operating results, cash flows and financial condition of Surmodics. The following discussion should be read together with our audited consolidated financial statements and related notes appearing elsewhere in this report. Any discussion and analysis regarding our future financial condition and results of operations are forward-looking statements that involve risks, uncertainties and assumptions, as more fully identified in "Forward-looking Statements" and "Risk Factors." Our actual future financial condition and results of operations may differ materially from those anticipated in the forward-looking statements.

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.

Merger Agreement

As described more fully under Part II, Item 8, Note 13 "Merger Agreement", on May 28, 2024, we entered into a Merger Agreement with BCE Parent, LLC, a Delaware limited liability company ("Parent"), and BCE Merger Sub, Inc., a Minnesota corporation and a wholly owned Subsidiary of Parent ("Merger Sub"), pursuant to which we will, subject to the terms and conditions of the Merger Agreement, be acquired by Parent for \$43.00 per share in cash through the merger of Merger Sub with and into us (the "Merger"), with Surmodics as the surviving corporation and a wholly owned subsidiary of Parent. If the Merger is consummated, shares of our common stock will be delisted from The Nasdaq Stock Market and deregistered under the Exchange Act.

The Merger was approved by Surmodics' shareholders at a special meeting on August 13, 2024. On the same date, the Company announced that it and an affiliate of Parent each received a request for additional information and documentary materials (a "Second Request") from the U.S. Federal Trade Commission ("FTC") in connection with the Merger. The Company and Parent are in the process of gathering information and documentary materials responsive to the Second Request and intend to continue to cooperate with the FTC in an effort to obtain expiration or termination of the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act") waiting period for the Merger as expeditiously as possible. As of the date of filing of this report, the Merger remained subject to the expiration or termination of the waiting period under the HSR Act, as well as other customary closing conditions. The Company and Parent expect to consummate the Merger in the Company's second fiscal quarter ending March 31, 2025, subject to customary closing conditions, including required regulatory approval.

In fiscal 2024, we incurred a total of \$3.7 million in Merger-related charges, which we reported within selling, general and administrative expense on the consolidated statements of operations.

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 that have been commercialized or are within our development pipeline. For our drug-coated balloon ("DCB") platform, we commercialized our SurVeil™ DCB through a distribution arrangement with Abbott Vascular, Inc. ("Abbott"). 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™ products platform.

Drug-coated Balloon Platform

Surmodics' DCBs are designed for vascular interventions to treat peripheral arterial disease ("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), which utilizes a proprietary paclitaxel drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity. In June 2023, the *SurVeil* DCB received premarket approval ("PMA") from the U.S. Food and Drug Administration ("FDA") and may now be marketed and sold in the U.S. by Abbott under our exclusive worldwide distribution agreement (the "Abbott Agreement").

In the first quarter of fiscal 2024, we completed shipment of Abbott's initial stocking order of commercial units of the *SurVeil* DCB, resulting in recognition of product sales, which included both (i) the contractual transfer price, and (ii) an estimate of Surmodics' share of net profits resulting from product sales by Abbott to third parties. Beginning in January 2024, the *SurVeil* DCB is a commercial product available in the U.S. through Abbott. Throughout fiscal 2024, we continued to manufacture and ship commercial units to Abbott in support of Abbott's commercialization of the product.

- **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. SWING study data at 24 months have demonstrated an excellent safety profile and promising signals of potential performance. We continue 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 and market interest.

Thrombectomy Systems

We have successfully developed, internally and through acquisitions, multiple FDA 510(k)-cleared mechanical thrombectomy devices, which require no capital equipment, for the non-surgical removal of thrombi and emboli (clots) from the peripheral arterial and venous vasculatures, while minimizing the need for thrombolytics. We believe that the ease of use, intuitive design, and performance of our thrombectomy systems make these products attractive first-line treatment options for interventionalists.

- **Pounce Thrombectomy Platform**, intended for the peripheral arterial vasculature, is a suite of mechanical thrombectomy systems designed for the capture and non-surgical removal of thrombi and emboli (clots) without the need for capital equipment or aspiration while minimizing the use of thrombolytics. Three different-sized systems are commercially available.

The original *Pounce* (mid profile) Thrombectomy System is indicated for use in peripheral arterial vessels 3.5 mm to 6 mm in diameter, such as those found above the knee. Commercial sales of the *Pounce* Thrombectomy System began in fiscal 2022.

The *Pounce* LP (Low Profile) Thrombectomy System is indicated for use in peripheral arterial vessels 2 mm to 4 mm in diameter, such as those found below the knee. The *Pounce* LP Thrombectomy System received FDA 510(k) regulatory clearance in the third quarter of fiscal 2023, and we began limited market evaluations of the product in the first quarter of fiscal 2024. In the third quarter of fiscal 2024, we completed limited market evaluations for the *Pounce* LP Thrombectomy System, and the product was commercially launched.

The *Pounce* XL Thrombectomy System is indicated for use in peripheral arterial vessels 5.5 mm to 10 mm in diameter, making it suitable for iliac, femoral, and other arteries within this range. The *Pounce* XL Thrombectomy System received FDA 510(k) regulatory clearance in the fourth quarter of fiscal 2024. We plan to initiate limited market evaluations of the product in the first half of fiscal 2025, with commercialization following the completion of the limited market evaluations.

- **Pounce Venous Thrombectomy System** is a mechanical thrombectomy system indicated for mechanical de-clotting and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral vasculature. The *Pounce* Venous Thrombectomy System is designed to remove mixed-morphology, wall-adherent venous clot in a single session, minimizing the need for thrombolytics and without the need for capital equipment. We conducted limited market evaluations of the *Pounce* Venous Thrombectomy System in fiscal 2023 and in the first half of fiscal 2024 to obtain physician feedback across a variety of cases and clinical conditions. In the second quarter of fiscal 2024, we completed limited market evaluations for the *Pounce* Venous Thrombectomy System, and the product was commercially launched.

Sublime Radial Access Platform

We have successfully developed and received FDA 510(k) regulatory clearance for a suite of devices designed to access and treat stenosed (narrowed) arteries from the thigh to the foot via radial (wrist) access. Our *Sublime* radial access platform provides a unique combination of length, profile and deliverability, allowing physicians to access and treat lesions previously inaccessible via radial access. Commercial sales of the *Sublime* guide sheath and RX PTA dilatation catheter devices began in fiscal 2022.

- **Sublime guide sheath** provides 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** treats lesions in peripheral arteries below the knee all the way to the patient's foot and around the pedal loop.
- **Sublime .018 RX PTA dilatation catheter** treats lesions in peripheral arteries above and below the knee.
- **Sublime microcatheters (.014, .018 and .035)** facilitate guidewire placement for difficult to access and treat arterial lesions above and below the knee using radial, femoral, or alternate access sites. Limited market evaluations of our *Sublime* microcatheters began in the third quarter of fiscal 2023. In the third quarter of fiscal 2024, we completed limited market evaluations for the *Sublime* microcatheter, and the product was commercially launched.

Performance Coatings – Preside™ Hydrophilic Coatings

In October 2023, we announced the commercial launch of our most advanced hydrophilic medical device coating technology, *Preside* hydrophilic coatings. *Preside* hydrophilic coatings complement our existing *Serene*™ hydrophilic coatings by providing customers with a unique low-friction and low-particulate generation coating to further enhance distal access for neuro-vascular applications, as well as improved crossing for challenging coronary lesions or chronic total occlusions. *Preside* hydrophilic coatings are specifically formulated to meet the challenge of achieving the right balance of enhanced lubricity (reduction in friction) and excellent coating durability (resulting in low particulates) for the next-generation of neurovascular, coronary and peripheral vascular devices. Our *Preside* and *Serene* hydrophilic coatings both allow customers to leverage their existing coating process to apply these innovative surface treatments.

For more information regarding our vascular intervention medical devices, see Part I, Item 1 of this Annual Report on Form 10-K.

Results of Operations

Fiscal Years Ended September 30, 2024, 2023 and 2022

Revenue. Fiscal 2024 revenue was \$126.1 million, a \$6.5 million or 5% decrease from fiscal 2023 revenue. Fiscal 2023 revenue was \$132.6 million, a \$32.6 million or 33% increase from fiscal 2022 revenue. In fiscal 2023, we received a \$27.0 million PMA milestone payment from Abbott, \$25.0 million of which was recognized as *SurVeil* DCB license fee revenue in the period. The following is a summary of revenue streams within each reportable segment.

<i>(Dollars in thousands)</i>	Fiscal Year			Increase/(Decrease)		Increase/(Decrease)		
	2024	2023	2022	2024 vs. 2023		2023 vs. 2022		
Medical Device								
Product sales	\$ 45,620	\$ 34,126	\$ 27,930	\$ 11,494	34%	\$ 6,196	22%	
Royalties & license fees – performance coatings	37,408	32,812	30,547	4,596	14%	2,265	7%	
License fees – <i>SurVeil</i> DCB	5,080	29,586	5,701	(24,506)	(83)%	23,885	419%	
R&D and other	9,400	9,259	8,211	141	2%	1,048	13%	
Medical Device Revenue	97,508	105,783	72,389	(8,275)	(8)%	33,394	46%	
In Vitro Diagnostics								
Product sales	27,970	26,488	26,691	1,482	6%	(203)	(1)%	
R&D and other	600	313	871	287	92%	(558)	(64)%	
In Vitro Diagnostics Revenue	28,570	26,801	27,562	1,769	7%	(761)	(3)%	
Total Revenue	\$ 126,078	\$ 132,584	\$ 99,951	\$ (6,506)	(5)%	\$ 32,633	33%	

Medical Device. Revenue in our Medical Device segment was \$97.5 million in fiscal 2024, an 8% decrease from \$105.8 million in fiscal 2023, primarily driven by lower *SurVeil* DCB license fee revenue, partly offset by growth in product sales and performance coating royalties and license fee revenue.

- Medical Device product revenue increased 34% to \$45.6 million in fiscal 2024, compared to \$34.1 million in fiscal 2023. Product sales growth year-over-year was primarily driven by fulfillment of the initial stocking order and subsequent orders for the *SurVeil* DCB from Abbott, our exclusive distribution partner for the product, and continued sales growth from the *Pounce* thrombectomy device platform.

Based on forecasts that we have received from Abbott for purchases of *SurVeil* DCB products, we expect product revenue for our *SurVeil* DCB products to decline by approximately \$5.0 million in fiscal 2025 from their fiscal 2024 level. We do not expect any increases in sales from our *Pounce* thrombectomy device platform to fully offset that decrease.

- Performance coating royalties and license fee revenue increased 14% to \$37.4 million in fiscal 2024, compared to \$32.8 million in fiscal 2023, driven primarily by continued growth in customer utilization of our *Serene* hydrophilic coating. In addition, fiscal 2024 performance coating royalties and license fee revenue benefited from \$1.4 million in catch-up payments received in the normal course of our customers reporting sales-based royalties.
- *SurVeil* DCB license fee revenue under the Abbott Agreement was \$5.1 million in fiscal 2024, compared to \$29.6 million in fiscal 2023. In fiscal 2023, we received a \$27.0 million milestone payment from Abbott upon receipt of PMA from the FDA for the *SurVeil* DCB, of which \$25.0 million was recognized as revenue in the period.

We anticipate completion of the TRANSCEND pivotal clinical trial in the second quarter of fiscal 2025. Consequently, we expect *SurVeil* DCB license fee revenue to decline by \$3.6 million in fiscal 2025, compared to fiscal 2024, with no further recognition of *SurVeil* DCB license fee revenue subsequent to March 31, 2025.

- Medical Device R&D and other revenue of \$9.4 million in fiscal 2024 was relatively flat, compared to fiscal 2023.

Medical Device. Revenue in our Medical Device segment was \$105.8 million in fiscal 2023, a 46% increase from \$72.4 million in fiscal 2022, primarily driven by higher *SurVeil* DCB license fee revenue and broad-based product sales growth.

- Medical Device product revenue increased 22% to \$34.1 million in fiscal 2023, compared to \$27.9 million in fiscal 2022. Product sales growth was primarily driven by increased sales of our *Pounce* thrombectomy and *Sublime* radial access platforms, performance coating reagents, and contract-manufactured balloon catheters, partly offset by decreased sales of proprietary specialty catheters due to the completion of a customer development program.
- Performance coating royalties and license fee revenue increased 7% to \$32.8 million in fiscal 2023, compared to \$30.5 million in fiscal 2022, driven by primarily by growth from customers utilizing our *Serene*™ coating. In addition, fiscal 2023 performance coating royalties and license fee revenue was impacted by macroeconomic factors to a lesser degree relative to the prior-year. Macroeconomic factors include pressure on procedure volumes from hospital capacity constraints and customer supply chain disruptions, as well as by customer devices maturing through their product life cycles.
- *SurVeil* DCB license fee revenue under the Abbott Agreement was \$29.6 million in fiscal 2023, compared to \$5.7 million in fiscal 2022. In fiscal 2023, we received a \$27.0 million milestone payment from Abbott upon receipt of PMA from the FDA for the *SurVeil* DCB, of which \$25.0 million was recognized as revenue in the period.
- Medical Device R&D and other revenue increased 13% to \$9.3 million in fiscal 2023, compared to \$8.2 million in fiscal 2022, driven by increased volume of performance coating services.

In Vitro Diagnostics. Revenue in our IVD segment was \$28.6 million in fiscal 2024, a 7% increase from \$26.8 million in fiscal 2023, driven primarily by growth in product revenue and R&D services revenue.

- IVD product revenue increased 6% to \$28.0 million in fiscal 2024, compared to \$26.5 million in fiscal 2023, primarily driven by strong customer demand for distributed antigen and microarray slide/surface products, partly offset by lower sales of colorimetric substrate products.
- IVD R&D and other revenue increased \$0.3 million to \$0.6 million in fiscal 2024, compared to \$0.3 million in fiscal 2023, related to customer development programs.

In Vitro Diagnostics. Revenue in our IVD segment was \$26.8 million in fiscal 2023, a 3% decrease from \$27.6 million in fiscal 2022, driven primarily by lower R&D services revenue and product revenue.

- IVD product revenue decreased 1% to \$26.5 million, compared to \$26.7 million in fiscal 2022, primarily driven by active management of inventory levels by certain customers. Sales of distributed antigen and protein stabilizer products declined year-over-year, partly offset by growth in sales of microarray slide/surface products.
- IVD R&D and other revenue was \$0.3 million in fiscal 2023, a decrease of \$0.6 million compared to \$0.9 million in fiscal 2022, driven by the completion of a customer development program.

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

<i>(Dollars in thousands)</i>	Fiscal Year			Increase/(Decrease)		Increase/(Decrease)	
	2024	2023	2022	2024 vs. 2023		2023 vs. 2022	
Product sales	\$ 73,590	\$ 60,614	\$ 54,621	\$ 12,976	21%	\$ 5,993	11%
Product costs	33,026	24,965	20,342	8,061	32%	4,623	23%
Product gross profit (1)	40,564	35,649	34,279	4,915	14%	1,370	4%
% Product gross margin (2)	55.1%	58.8%	62.8%	(3.7) ppt		(4.0) ppt	
Research and development	38,360	46,595	50,609	(8,235)	(18)%	(4,014)	(8)%
% Total revenue	30%	35%	51%				
Selling, general and administrative	56,836	51,884	46,935	4,952	10%	4,949	11%
% Total revenue	45%	39%	47%				
Acquired intangible asset amortization	3,501	3,537	4,150	(36)	(1)%	(613)	(15)%
Restructuring expense	—	1,282	—	(1,282)		1,282	
Contingent consideration (gain) expense	—	(829)	12	829		(841)	

(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 55.1%, 58.8% and 62.8% in fiscal 2024, 2023 and 2022, respectively.

- Fiscal 2024 product gross margin was 55.1%, compared to 58.8% in the prior year. The year-over-year decrease in product gross margin was primarily related to *SurVeil* DCB products during their initial commercialization. In fiscal 2024, manufacturing of *SurVeil* DCB products was not at scale, and fiscal 2024 product gross margin was impacted by the associated under-absorption and production inefficiencies, including expiration of raw materials inventory. In addition, fiscal 2024 product gross margin reflected an adverse mix impact from the year-over-year increase in sales of relatively lower margin products as a proportion of total product sales. These unfavorable impacts were partly offset by the year-over-year increase in product sales and gross profit from our *Pounce* thrombectomy and *Sublime* radial access device platforms, which had a favorable year-over-year impact to product gross margin in fiscal 2024, primarily driven by leverage on increased sales volume and improvements in production efficiency.

In fiscal 2025, we expect product gross profit and product gross margin to decline, compared their fiscal 2024 levels, primarily due to the expected decline in fiscal 2025 *SurVeil* DCB product revenue resulting in the under-absorption and production inefficiencies associated with below-scale production, including potential expiration of inventory. We do not expect any increases in product gross profit from our *Pounce* thrombectomy device platform to fully offset that decrease.

- Fiscal 2023 product gross margin was 58.8%, compared to 62.8% in the prior year. The decrease in product gross margin was primarily driven by the adverse mix impact from increased device product sales, which have lower product gross margins from under-absorption and production inefficiencies, including expiration of inventory, associated with low production volumes during the scale-up phase following initial commercialization.

Research and development expense. R&D expense was \$38.4 million, \$46.6 million and \$50.6 million in fiscal 2024, 2023 and 2022, respectively.

- Fiscal 2024 R&D expense decreased by \$8.2 million year-over-year and was 30% of revenue, compared to 35% of revenue in fiscal 2023. The year-over-year decrease in R&D expense was primarily driven by lower *SurVeil* DCB R&D expenses due to the transition to commercialization and lower thrombectomy platform R&D expenses due to the timing of development and commercialization of device products. The spending reduction plan and workforce reduction implemented in the second quarter of fiscal 2023 also contributed to the year-over-year decrease in R&D expense in fiscal 2024. For fiscal 2023, R&D expense as a percentage of revenue reflects the impact of higher revenue, principally from the \$25.0 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.
- Fiscal 2023 R&D expense decreased by \$4.0 million year-over-year and was 35% of revenue, compared to 51% of revenue in fiscal 2022. The decline in R&D expense as a percentage of revenue reflects the impact of higher revenue in fiscal 2023, principally from the \$25.0 million in *SurVeil* DCB 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 was the primary driver of the year-over-year decrease in R&D expense. For both fiscal 2023 and 2022, R&D expense reflected 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 expense. SG&A expense was \$56.8 million, \$51.9 million and \$46.9 million in fiscal 2024, 2023 and 2022, respectively.

- Fiscal 2024 SG&A expense increased by \$5.0 million year-over-year and was 45% of revenue, compared to 39% of revenue in fiscal 2023. The year-over-year increase in SG&A expense was primarily driven by \$3.7 million in Merger-related charges, as well as increased sales compensation expenses. In fiscal 2023, SG&A expense as a percentage of revenue reflects the impact of higher revenue, principally from the \$25.0 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.
- Fiscal 2023 SG&A expense increased by \$4.9 million year-over-year and was 39% of revenue, compared to 47% of revenue in fiscal 2022. The decline in SG&A expense as a percentage of revenue reflects the impact of higher revenue in fiscal 2023, principally from the \$25.0 million in *SurVeil* DCB license fee revenue recognized in fiscal 2023 upon receipt of the \$27.0 million *SurVeil* DCB PMA milestone payment under the Abbott Agreement. In fiscal 2023, the year-over-year increase in SG&A expense was primarily driven by increased compensation and sales and marketing expenses.

Acquired intangible asset amortization. We have previously acquired certain intangible assets through business combinations, which are amortized over periods ranging from seven to 14 years. Fiscal 2024 acquired intangible asset amortization was consistent with the prior year. In fiscal 2023, acquired intangible asset amortization declined compared to the prior year primarily as the result of certain intangible assets having been fully amortized.

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 fiscal 2023, we recorded \$1.3 million in severance and related charges in restructuring expense, all of which was paid in fiscal 2023.

Contingent consideration (gain) expense. In fiscal 2023, we reported a \$(0.8) million 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, net. Major classifications of other expense were as follows:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Interest expense, net	\$ (3,540)	\$ (3,489)	\$ (598)
Foreign exchange (loss) gain	(243)	(251)	103
Investment income, net	1,922	1,077	99
Other expense, net	\$ (1,861)	\$ (2,663)	\$ (396)

Interest expense, net in fiscal 2024 was relatively consistent with the prior year. In fiscal 2023, the increase in interest expense, net compared to the prior year was primarily due to increased borrowings and higher interest rates. 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. In fiscal 2024 and 2023, investment income, net increased compared to the respective prior-year periods due to an increase in average balances of cash equivalents and available-for-sale investments, as well as higher interest rates.

Income tax expense. (Loss) income before income taxes, income tax expense and our effective tax rate were as follows:

<i>(Dollars in thousands)</i>	Fiscal Year		
	2024	2023	2022
(Loss) income before income taxes	\$ (7,506)	\$ 2,487	\$ (22,493)
Income tax expense	(4,036)	(4,023)	(4,781)
Effective tax rate	(54) %	162 %	(21) %

- 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. In fiscal 2024 and 2023, this change impacted U.S. federal and state income tax expense and cash taxes paid.
- 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, resulting in a non-cash charge to income tax expense of \$10.2 million. In fiscal 2024 and 2023, we maintained the full valuation allowance against our net U.S. deferred tax assets. As a result of the full valuation allowance, in fiscal 2024 and 2023, we are no longer recording a tax benefit associated with U.S. pre-tax 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 U.S. federal and Irish R&D credits, excess tax benefits associated with stock-based compensation, Irish and U.S. state tax rates, foreign-derived intangible income deductions in the U.S., and non-deductible merger-related charges.

Segment Operating Results

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

<i>(In thousands)</i>	Fiscal Year			Increase/(Decrease)	
	2024	2023	2022	2024 vs. 2023	2023 vs. 2022
Operating (loss) income:					
Medical Device	\$ (2,239)	\$ 5,084	\$ (22,923)	\$ (7,323)	\$ 28,007
In Vitro Diagnostics	13,101	12,637	13,073	464	(436)
Total segment operating income (loss)	10,862	17,721	(9,850)	(6,859)	27,571
Corporate	(16,507)	(12,571)	(12,247)	(3,936)	(324)
Total operating (loss) income	\$ (5,645)	\$ 5,150	\$ (22,097)	\$ (10,795)	\$ 27,247

Medical Device. Our Medical Device business reported an operating loss of \$(2.2) million in fiscal 2024, compared to operating income of \$5.1 million in fiscal 2023, representing (2)% and 5% of Medical Device revenue in fiscal 2024 and 2023, respectively.

- SurVeil* DCB license fee revenue decreased \$24.5 million year-over-year in fiscal 2024. In fiscal 2023, we received a \$27.0 million milestone payment from Abbott upon receipt of PMA from the FDA for the *SurVeil* DCB, of which \$25.0 million was recognized as revenue in the period.
- Medical Device operating expenses, excluding product costs, decreased \$7.9 million year-over-year in fiscal 2024. Fiscal 2023 included a \$(0.8) million gain from the fair value adjustment of acquisition-related contingent consideration, partly offset by \$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 fiscal 2024, driven primarily by lower R&D expenses associated with *SurVeil* DCB products due to the transition to commercialization and lower thrombectomy platform R&D expenses due to the timing of development and commercialization of device products. The spending reduction plan and workforce reduction implemented in the second quarter of fiscal 2023 also contributed to the year-over-year decrease in R&D expense in fiscal 2024. SG&A expense in our Medical Device business increased modestly in fiscal 2024, compared to fiscal 2023, primarily driven by higher sales compensation expenses.

- Performance coating royalties and license fee revenue increased \$4.6 million year-over-year in fiscal 2024, driven by primarily by continued growth in customer utilization of our *Serene* hydrophilic coating. In addition, fiscal 2024 performance coating royalties and license fee revenue benefited from \$1.4 million in catch-up payments received in in the normal course of our customers reporting sales-based royalties.
- Medical Device product gross profit increased \$4.5 million year-over-year in fiscal 2024 on increased product revenue, and product gross margins were 49.5% and 52.9% for fiscal 2024 and 2023, respectively. The year-over-year decrease in product gross margin was primarily related to *SurVeil* DCB products during the production volumes following initial commercialization. In fiscal 2024, manufacturing of the *SurVeil* DCB products was not at scale, and fiscal 2024 product gross margin was impacted by the associated under-absorption and production inefficiencies, including expiration of raw materials inventory. In addition, fiscal 2024 Medical Device product gross margin reflected the adverse mix impact from the year-over-year increase in relatively lower margin device product sales as a proportion of total product sales. These unfavorable impacts were partly offset by the year-over-year increase in product sales and gross profit from our *Pounce* thrombectomy and *Sublime* radial access device platforms, which had a favorable year-over-year impact to product gross margin in fiscal 2024, primarily driven by leverage on increased sales volume and improvements in production efficiency.

In fiscal 2025, we expect Medical Device product gross profit and product gross margin to decline, compared their fiscal 2024 levels, primarily due to the expected decline in fiscal 2025 *SurVeil* DCB product revenue as a result of the under-absorption and production inefficiencies associated with below-scale production, including potential expiration of inventory. We do not expect any increases in product gross profit from our *Pounce* thrombectomy device platform to fully offset that decrease.

Medical Device. Our Medical Device business reported operating income of \$5.1 million in fiscal 2023, compared to an operating loss of \$(22.9) million in fiscal 2022, representing 5% and (32)% of Medical Device revenue in fiscal 2023 and 2022, respectively.

- *SurVeil* DCB license fee revenue increased \$23.9 million year-over-year in fiscal 2023. In fiscal 2023, we received a \$27.0 million milestone payment from Abbott upon receipt of PMA from the FDA for the *SurVeil* DCB, of which \$25.0 million was recognized as revenue in the period.
- Performance coating royalties and license fee revenue increased \$2.3 million year-over-year in fiscal 2023, primarily driven by growth from customers utilizing our *Serene*[™] coating and the diminished impact of macroeconomic factors on procedure volumes.
- Medical Device product gross profit increased \$1.5 million year-over-year in fiscal 2023 on increased product revenue, and product gross margins were 52.9% and 59.2% for fiscal 2023 and 2022, respectively. The decrease in product gross margin was primarily driven by the adverse mix impact from increased device product sales, which have lower product gross margins from under-absorption and production inefficiencies, including expiration of inventory, associated with low production volumes during the scale-up phase following initial commercialization.
- Medical Device operating expenses, excluding product costs, increased \$0.7 million year-over-year in fiscal 2023. Fiscal 2023 included \$1.3 million in severance-related restructuring expense as the result of a workforce restructuring, partly offset by a \$(0.8) million gain from the fair value adjustment of acquisition-related contingent consideration. SG&A expense in the Medical Device business increased \$3.5 million year-over-year in fiscal 2023, primarily driven by increased compensation and sales and marketing expenses. R&D expenditures in our Medical Device segment declined year-over-year in fiscal 2023, driven primarily by the spending reduction plan implemented in the second quarter of fiscal 2023. The spending reduction plan, which included a workforce restructuring, was designed to refocus our investments in product development to prioritize progress primarily on our near-term growth opportunities. For both fiscal 2023 and 2022, R&D expense reflected 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.

In Vitro Diagnostics. Our IVD business reported operating income of \$13.1 million in fiscal 2024, an increase of 4% or \$0.5 million compared to fiscal 2023. IVD operating income was 46% and 47% of revenue in fiscal 2024 and 2023, respectively.

- IVD product gross profit increased 2%, or \$0.4 million, in fiscal 2024, compared to the prior year, on increased product sales volume. IVD product gross margins were 64.2% and 66.4% for fiscal 2024 and 2023, respectively. The year-over-year decrease in product gross margin was primarily attributable to the unfavorable impact of product mix from growth in sales of relatively lower margin distributed antigen products.
- R&D and other revenue increased \$0.3 million in fiscal 2024, compared to the prior year, related to customer development programs.
- IVD operating costs and expenses, excluding product costs, increased \$0.2 million in fiscal 2024, compared to the prior year.

In Vitro Diagnostics. Our IVD business reported operating income of \$12.6 million in fiscal 2023, a decrease of 3% or \$0.4 million compared to fiscal 2022. IVD operating income was 47% of revenue in both fiscal 2023 and 2022.

- R&D and other revenue decreased \$0.6 million in fiscal 2023, compared to the prior year, due to the completion of a customer development program.
- IVD product gross profit decreased 1%, or \$0.1 million, in fiscal 2023, compared to the prior year, on decreased product sales volume. IVD product gross margins were 66.4% and 66.5% for fiscal 2023 and 2022, respectively.
- IVD operating costs and expenses, excluding product costs, decreased \$0.3 million in fiscal 2023, compared to the prior year.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive management, corporate accounting, legal, information technology, 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 litigation and Merger-related costs, which are not specific to a segment and thus not allocated to our reportable segments. The unallocated Corporate operating loss was \$(16.5) million, \$(12.6) million and \$(12.2) million in fiscal 2024, 2023 and 2022, respectively. The year-over-year increase in Corporate operating loss in fiscal 2024 of \$3.9 million, or 31%, was primarily driven by \$3.7 million in Merger-related charges reported in SG&A expense. In fiscal 2023, the year-over-year increase in Corporate expense of \$0.4 million, or 3%, was primarily related to increased compensation expenses.

Cash Flow Operating Results

The following is a summary of cash flow results:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Cash provided by (used in)			
Operating activities	\$ 248	\$ 10,514	\$ (17,223)
Investing activities	(2,937)	(6,822)	6,230
Financing activities	(2,950)	18,406	(375)
Effect of exchange rates on changes in cash and cash equivalents	335	323	(787)
Net change in cash and cash equivalents	\$ (5,304)	\$ 22,421	\$ (12,155)

Operating Activities. Cash provided by (used in) operating activities totaled \$0.2 million, \$10.5 million and \$(17.2) million in fiscal 2024, 2023 and 2022, respectively. During fiscal 2024, 2023 and 2022, we reported net loss of \$(11.5) million, \$(1.5) million and \$(27.3) million, respectively. Net changes in operating assets and liabilities reduced cash flows from operating activities by \$(5.4) million, \$(4.2) million and \$(12.3) million in fiscal 2024, 2023 and 2022, respectively.

Significant changes in operating assets and liabilities affecting cash flows during fiscal 2024, 2023 and 2022 included:

- Cash provided by (used in) prepaids and other assets was \$4.9 million, \$0.0 million and \$(0.7) million in fiscal 2024, 2023 and 2022, respectively. In fiscal 2024, the year-over-year increase in cash provided was driven primarily by the collection of a \$3.4 million receivable in the second quarter of fiscal 2024, which had been recorded at the end of fiscal 2021, associated with the employee retention credit under the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”).
- Cash used in accounts receivable and contract assets was \$(5.2) million, \$(1.0) million and \$(1.5) million fiscal 2024, 2023 and 2022, respectively. In fiscal 2024, the year-over-year increase in cash used was primarily driven by increased accounts receivable on year-over-year revenue growth, contract assets recognized on *SurVeil* DCB product sales to Abbott, and increased contract assets recorded for growth in sales-based royalties.
- Cash used in inventories was \$(0.3) million, \$(3.0) million and \$(5.1) million in fiscal 2024, 2023 and 2022, respectively. In fiscal 2024, the year-over-year decrease in cash used was the result of active management of working capital in inventory. Fiscal 2023 and 2022 cash used in inventories was primarily driven by the commercialization of *Pounce* and *Sublime* product platforms in our Medical Device business. In fiscal 2023, cash used in inventories was also driven by commercial readiness activities for the launch of the *SurVeil* DCB product by our exclusive distribution partner, Abbott, following receipt of FDA approval in June 2023. In fiscal 2022, prudent management of safety stock to mitigate supply chain risks also contributed to cash used in inventories.
- Cash used in deferred revenue was \$(5.2) million, \$(2.5) million and \$(5.7) million in fiscal 2024, 2023 and 2022, respectively, and was driven primarily by *SurVeil* DCB license fee revenue recognition of \$5.1 million, \$29.6 million and \$5.7 million in fiscal 2024, 2023 and 2022, respectively. In fiscal 2023, this was partly offset by the receipt of a \$27.0 million milestone payment from Abbott upon receipt of PMA from the FDA for the *SurVeil* DCB.

- In addition, income taxes affected the change in operating assets and liabilities. In fiscal 2024, cash provided by income taxes of \$1.6 million was primarily driven by the year-over-year increase in income tax payable. In fiscal 2023, cash provided by income taxes of \$3.4 million was driven primarily by the receipt of a \$2.3 million tax refund under the CARES Act. In fiscal 2022, cash used in income taxes of \$(1.1) million was primarily driven by the year-over-year increase in income tax receivable. Cash taxes paid were \$2.6 million, \$2.9 million and \$0.4 million in fiscal 2024, 2023 and 2022, respectively.

Investing Activities. Cash (used in) provided by investing activities was \$(2.9) million, \$(6.8) million and \$6.2 million in fiscal 2024, 2023 and 2022, respectively.

- We invested \$3.5 million, \$2.9 million and \$3.4 million in property and equipment in fiscal 2024, 2023 and 2022, respectively.
- Net purchases and maturities of available-for-sale investments were a source (use) source of cash totaling \$0.5 million, \$(3.9) million and \$9.6 million in fiscal 2024, 2023 and 2022, respectively.

Financing Activities. Cash (used in) provided by financing activities totaled \$(3.0) million, \$18.4 million and \$(0.4) million in fiscal 2024, 2023 and 2022, respectively.

- In fiscal 2024, we paid \$1.7 million in deferred consideration related to the fiscal 2021 acquisition of Vetex Medical Limited (“Vetex”).
- In 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.
- In fiscal 2024, 2023 and 2022, we paid \$1.5 million, \$0.9 million and \$1.1 million, respectively, to purchase common stock to pay employee taxes resulting from the exercise of stock options and vesting of other stock awards.
- In fiscal 2024, 2023 and 2022, we generated \$1.2 million, \$1.3 million and \$1.2 million, respectively, from the sale of common stock related to our stock-based compensation plans.
- In fiscal 2024, 2023 and 2022, we paid \$0.9 million, \$1.0 million and \$0.5 million, respectively, for acquisition of in-process R&D.

Liquidity and Capital Resources

As of September 30, 2024, working capital totaled \$60.8 million, a decrease of \$2.0 million from September 30, 2023. We define working capital as current assets minus current liabilities. Cash and cash equivalents and available-for-sale investments totaled \$40.1 million as of September 30, 2024, a decrease of \$5.3 million from \$45.4 million as of September 30, 2023.

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 \$19.3 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 September 30, 2024, the outstanding balance on the revolving credit facility was \$5 million. As of September 30, 2024, additional, incremental availability on the revolving credit facility was approximately \$14.6 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 if certain conditions are met. As of September 30, 2024, 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. An additional 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 the 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 September 30, 2024, 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 fiscal 2025, we anticipate SG&A and R&D expenses will continue to be significant, primarily related to medical device sales and product development, including continued investment in our *Pounce* and *Sublime* product platforms. We believe that our existing cash and cash equivalents and available-for-sale investments, which totaled \$40.1 million as of September 30, 2024, 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 2025. There can be no assurance, however, that our business will continue to generate cash flows at historic levels.

Beyond fiscal 2025, 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 *SurVeil* DCB distributed 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 cashflow. There can be no assurance that such transactions will be available to us on favorable terms, if at all.

Below is a summary of short-term and long-term anticipated cash requirements under contractual obligations existing as of September 30, 2024.

(In millions)	September 30, 2024		
	Total	Fiscal 2025	After Fiscal 2025
Operating leases (1)	\$ 4.0	\$ 1.2	\$ 2.8
Acquisition-related obligations (2)	1.8	—	1.8
Total gross value	<u>\$ 5.8</u>	<u>\$ 1.2</u>	<u>\$ 4.6</u>

(1) The Company leases facilities for research, office, manufacturing and warehousing.

(2) Acquisition-related obligations consist of the gross value of the final remaining guaranteed milestone payment to be made in association with the fiscal 2021 Vetex acquisition, excluding amounts that are contingent upon unmet product development and regulatory milestones.

For additional information regarding the above obligations, see Notes 2 and 11 to the consolidated financial statements in "Financial Statements and Supplementary Data" in Part II, Item 8 of this Annual Report on Form 10-K.

As of September 30, 2024, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures, or capital resources that is material to investors.

Share Repurchase Authorization

Our Board of Directors has authorized the repurchase of up to an additional \$25.3 million of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of such methods. The authorization has no fixed expiration date. However, both the Merger Agreement and our credit agreement with MidCap restricts us from acquiring outstanding shares of the Company's common stock. We did not repurchase any shares of our common stock under this authorization in fiscal 2024.

Customer Concentrations

Revenue from customers that equaled or exceeded 10% of total revenue was as follows:

	Fiscal Year		
	2024	2023	2022
Abbott	16%	27%	11%
Medtronic	12%	10%	13%

We have agreements with a diverse base of customers, and certain customers have multiple products licensed to use our technology. Abbott and Medtronic plc (“Medtronic”) are our largest customers. Abbott has several separately licensed products, including the *SurVeil* DCB license, which generate revenue for Surmodics. Total revenue associated with our *SurVeil* DCB, including license fee revenue and product sales from shipment of commercial units of the *SurVeil* DCB to Abbott, represented 10%, 22% and 6% of total revenue for fiscal 2024, 2023 and 2022, respectively. Apart from the *SurVeil* DCB license, Abbott has several separately licensed products which generate revenue for Surmodics, none of which represented more than 4% of our total revenue for fiscal 2024. Medtronic has several separately licensed products that generate royalties revenue for Surmodics, none of which represented more than 5% of our total revenue for fiscal 2024.

Our licensing agreements with many of our customers, including most of our significant customers, cover many licensed products that each separately generates royalties and license fee revenue. This structure reduces the potential risk to our operations that may result from reduced sales (or the termination of a license) of a single product for any specific customer.

New Accounting Pronouncements

Information regarding new accounting pronouncements is included in Note 2 to the consolidated financial statements in “Financial Statements and Supplementary Data” in Part II, Item 8 of this Annual Report on Form 10-K.

Critical Accounting Policies and Significant Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. (“GAAP”). The preparation of these consolidated financial statements is based in part on the application of significant accounting policies, many of which require management to make estimates and assumptions; see Notes 1 and 2 to the consolidated financial statements in “Financial Statements and Supplementary Data” in Part II, Item 8 of this Annual Report on Form 10-K. Actual results may differ from these estimates and such differences could materially impact our financial condition and results of operations.

Critical accounting policies and significant estimates are those judgments that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition and results of operations. They 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 and significant estimates involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. We believe the following are critical areas in the application of our accounting policies and estimates that currently affect our financial condition and results of operations.

Revenue Recognition

We license technology to medical device manufacturers (third parties) and collect royalties based on the greater of the contractual percentage of a customer’s sales of products incorporating our licensed technologies or minimum contractual royalties. Sales-based royalties revenue is recognized as our license customers sell products containing our technologies, which is generally reported to us a quarter after those sales occur. This requires us to estimate the revenue earned on these arrangements and record it prior to our customers reporting the underlying sales to us. Sales-based royalties are estimated using the most-likely amount method based on historical sales information, adjusted for known changes, such as product launches and patent expirations. We also consider macroeconomic factors affecting the medical device market. These inputs require significant management judgment and are updated quarterly. Minimum royalty fees are recognized through the non-cancellable period, which is generally 90 days, but can be up to one year. Revenue related to contingent milestones is recognized upon the achievement of the milestone, provided collectability is assured. Customer advances are accounted for as a liability (deferred revenue) until all criteria for revenue recognition have been met.

SurVeil DCB license fee revenue under our license and development agreement with Abbott is recognized as the clinical and regulatory activities are performed and control is transferred, which is measured based on actual costs incurred relative to the expected total cost of the underlying activities, which consist of the TRANSCEND clinical trial. A significant component of the cost of this trial is the cost of our outsourced clinical trial CRO consultants, which are estimated based on executed statements of work, project budgets, and patient enrollment and follow-up timing, among other things. Costs related to the clinical and regulatory activities are expensed in the period incurred. A significant change to our estimate of the costs to complete the TRANSCEND clinical trial could have a material effect on our results of operations. The total expected cost of the trial is a significant management estimate and is reviewed and assessed each reporting period. The current portion of deferred revenue on the consolidated balance sheet represents the amount of deferred revenue that is expected to be recognized over the next year, based on estimated costs to be incurred. The estimate of future license fee revenue from the Abbott Agreement will continue to be monitored and adjusted based on estimates in effect each period-end. For further disclosures related to revenue recognition, see Notes 2, 3 and 4 to the consolidated financial statements in “Financial Statements and Supplementary Data” in Part II, Item 8 of this Annual Report on Form 10-K.

Goodwill and Definite-lived Intangible Assets

Our estimates associated with the annual test of goodwill for impairment, as well as the as-needed assessment of the recoverability of definite-lived intangible assets, are considered critical due to the amount of these assets recorded on our consolidated balance sheets and the judgment required.

We record all assets and liabilities acquired in business acquisitions at fair value, including goodwill and other intangible assets. The initial recognition of goodwill and other intangible assets requires management to make subjective judgments concerning estimates of how the acquired assets will perform in the future using valuation methods including discounted cash flow analysis.

Goodwill represents the excess of the purchase price of an acquired business over the fair value assigned to the assets purchased and liabilities assumed. Goodwill is not amortized but is subject, at a minimum, to annual tests for impairment in accordance with accounting guidance for goodwill. The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change indicating that it is more likely than not that the fair value of a reporting unit is less than its carrying amount.

Our reporting units are the Medical Device and In Vitro Diagnostics reportable segments. To determine if goodwill is potentially impaired, we have the option to perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If we elect not to conduct the qualitative assessment or if indications of a potential impairment exist, the determination of whether an impairment has occurred requires the fair value of each reporting unit to be assessed by performing a quantitative assessment. Inherent in the determination of fair value of the reporting units are certain estimates and judgments, including the interpretation of current economic indicators and market valuations, as well as management's strategic plans with regard to its operations.

Under the qualitative assessment, we consider several factors, including the business enterprise value of the reporting unit from the last quantitative test and the excess of fair value over carrying value from this test, macroeconomic conditions, industry and market considerations, the recent and projected financial performance of the reporting unit, as well as other factors.

Under the quantitative assessment, we determine fair value at the reporting unit level based on a combination of an income approach and market approach. The income approach is based on estimated future cash flows, discounted at a rate that approximates the cost of capital of a market participant, while the market approach is based on sales and/or earnings multiples of similar companies. These approaches use significant estimates and assumptions, including projected future cash flows and the timing of those cash flows, discount rates reflecting risks inherent in future cash flows, perpetual growth rates, and determination of appropriate market comparables.

We perform our annual assessment of goodwill for impairment as of July 1st of each fiscal year. Goodwill was not impaired in either reporting unit based on the outcome of the fiscal 2024 annual impairment test, which utilized a qualitative assessment. No goodwill impairment charges were recorded in fiscal 2024, 2023 and 2022.

With respect to definite-lived intangible assets, we periodically evaluate whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of such assets. If such events or circumstances indicate that the carrying amount of these assets may not be recoverable, management would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) were less than the carrying amount of the assets, we would recognize an impairment charge to reduce such assets to their fair value. In fiscal 2024, 2023 and 2022, no impairment charges were recorded related to our definite-lived intangible assets.

Income Taxes

Significant judgment is required in evaluating our tax positions and in determining income tax expense, deferred tax assets and liabilities, and any valuation allowance recorded against our deferred tax assets. We evaluate the recoverability of deferred tax assets based on available evidence. This process involves significant management judgment about assumptions that are subject to change from period to period based on changes in tax laws or variances between future projected operating performance and actual results. Under GAAP, we establish a valuation allowance for deferred tax assets if we determine, based on available evidence at the time the determination is made, that it is more likely than not (defined as a likelihood of more than 50%) that all or a portion of the deferred tax assets will not be realized. In making this determination, we evaluate all positive and negative evidence as of the end of each reporting period. Future adjustments (either increases or decreases) to the deferred tax asset valuation allowance are determined based upon changes in the expected realization of the net deferred tax assets. In fiscal 2022, we recorded a non-cash charge to income tax expense of \$10.2 million that resulted from the establishment of a full valuation allowance against U.S. net deferred tax assets as of September 30, 2022. In fiscal 2024 and 2023, we maintained the full valuation allowance against our net U.S. deferred tax assets. The realization of the deferred tax assets ultimately depends on the existence of sufficient taxable income or tax liability in either the carry-back or carry-forward periods under the tax law. 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.

We establish reserves for uncertain tax positions when, despite our belief that our tax return positions are fully supportable, we believe that certain positions are likely to be challenged and that we may or may not prevail. Under GAAP, if we determine that a tax position is more likely than not of being sustained upon audit, based solely on the technical merits of the position, we recognize the benefit. We measure the benefit by determining the amount that is greater than 50% likely of being realized upon settlement. We presume that all tax positions will be examined by a taxing authority with full knowledge of all relevant information. The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We regularly monitor our tax positions and tax liabilities. We reevaluate the technical merits of our tax positions and recognize an uncertain tax benefit, or derecognize a previously recorded tax benefit, when there is (i) a completion of a tax audit, (ii) effective settlement of an issue, (iii) a change in applicable tax law including a tax case or legislative guidance, or (iv) the expiration of the applicable statute of limitations. Significant judgment is required in accounting for tax reserves. Although we believe that we have adequately provided for liabilities resulting from tax assessments by taxing authorities, positions taken by these tax authorities could have a material impact on our results of operations.

ITEM 7A. 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 September 30, 2024, we held \$4.0 million in available-for-sale debt securities with maturity dates of less than one year. 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 operation 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 addition, the transfer price paid by Abbott for units of our *SurVeil* DCB product is denominated in Euros. 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Surmodics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Surmodics, Inc. and subsidiaries (the "Company") as of September 30, 2024 and 2023, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows, for each of the three years in the period ended September 30, 2024, and the related notes and the schedule listed in the Table of Contents at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2024, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of September 30, 2024, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated November 20, 2024, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Royalties and license fees – Q4 Sales-based Royalty Estimate — Refer to Note 2 of the financial statements

Critical Audit Matter Description

Royalty revenue consists of sales-based royalties estimates under licenses of performance coating technologies. Performance obligations under these licenses, which consist of the right to use the Company's proprietary technology, are satisfied at a point in time corresponding with delivery of the underlying technology rights to the customer, which is generally upon transfer of the licensed technology to the customer. Sales-based royalty revenue represents variable consideration under the license agreements and is recognized in the period a customer sells products incorporating the Company's licensed technologies. The variable consideration is generally reported to the Company in the quarter after these sales occur. The Company estimates sales-based royalty revenue earned but unpaid at each reporting period using the expected value method based on historical sales information, adjusted for known changes such as product launches and patent expirations. The Company also considers macroeconomic factors affecting the medical device market. These inputs require significant management judgment.

Given the significant judgments made by management relating to the inputs used in the expected value method to estimate the sales-based royalties earned under licenses of performance coating technologies that are earned but unpaid in the final quarter of the fiscal year, auditing such inputs required an increased extent of audit effort and a high degree of auditor judgment when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Q4 sales-based royalty estimate under licenses of performance coating technologies included the following, among others:

- We tested the effectiveness of controls over the Q4 sales-based royalty estimate.
- We tested management's process through inquiries of management and inspection of the inputs used in the expected value method to understand how management developed the Q4 sales-based royalty estimate under licenses of performance coating technologies.
- We evaluated and tested the expected value method inputs including historical sales information, adjustments for product launches, patent expirations, and macroeconomic factors in the Q4 sales-based royalty estimate and compared prior period management estimates to actual royalty revenue reported by customers.
- We tested select license agreements between the Company and customers, which included inspection of quarterly reporting from customers, to evaluate the accuracy and completeness of the historical information included within the Q4 sales-based royalty estimate.
- We tested the mathematical accuracy of the Q4 sales-based royalty estimate used for revenue recognition.

/s/ Deloitte & Touche LLP

Minneapolis, Minnesota
November 20, 2024

We have served as the Company's auditor since 2002.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Surmodics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Surmodics, Inc. and subsidiaries (the “Company”) as of September 30, 2024, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2024, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended September 30, 2024, of the Company and our report dated November 20, 2024, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Minneapolis, Minnesota
November 20, 2024

Surmodics, Inc. and Subsidiaries
Consolidated Balance Sheets
As of September 30,

<i>(In thousands, except per share data)</i>	2024	2023
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 36,115	\$ 41,419
Available-for-sale securities	3,997	3,933
Accounts receivable, net of allowances of \$144 and \$80 as of September 30, 2024 and 2023, respectively	13,292	10,850
Contract assets	9,872	7,796
Inventories	15,168	14,839
Income tax receivable	—	491
Prepays and other	2,860	7,363
Total Current Assets	81,304	86,691
Property and equipment, net	24,956	26,026
Intangible assets, net	23,569	26,206
Goodwill	44,640	42,946
Other assets	4,093	3,864
Total Assets	<u>\$ 178,562</u>	<u>\$ 185,733</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,786	\$ 2,993
Accrued liabilities:		
Compensation	11,099	10,139
Accrued other	3,795	6,444
Deferred revenue	1,619	4,378
Income tax payable	1,244	—
Total Current Liabilities	20,543	23,954
Long-term debt, net	29,554	29,405
Deferred revenue, less current portion	—	2,400
Deferred income taxes	1,785	2,004
Other long-term liabilities	7,783	8,060
Total Liabilities	<u>59,665</u>	<u>65,823</u>
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; 14,325 and 14,155 shares issued and outstanding, as of September 30, 2024 and 2023, respectively	716	708
Additional paid-in capital	44,594	36,706
Accumulated other comprehensive loss	(2,126)	(4,759)
Retained earnings	75,713	87,255
Total Stockholders' Equity	<u>118,897</u>	<u>119,910</u>
Total Liabilities and Stockholders' Equity	<u>\$ 178,562</u>	<u>\$ 185,733</u>

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

Surmodics, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Fiscal Year Ended September 30,

<i>(In thousands, except per share data)</i>	2024	2023	2022
Revenue:			
Product sales	\$ 73,590	\$ 60,614	\$ 54,621
Royalties and license fees	42,488	62,398	36,248
Research, development and other	10,000	9,572	9,082
Total revenue	126,078	132,584	99,951
Operating costs and expenses:			
Product costs	33,026	24,965	20,342
Research and development	38,360	46,595	50,609
Selling, general and administrative	56,836	51,884	46,935
Acquired intangible asset amortization	3,501	3,537	4,150
Restructuring expense	—	1,282	—
Contingent consideration (gain) expense	—	(829)	12
Total operating costs and expenses	131,723	127,434	122,048
Operating (loss) income	(5,645)	5,150	(22,097)
Other expense:			
Interest expense, net	(3,540)	(3,489)	(598)
Foreign exchange (loss) gain	(243)	(251)	103
Investment income, net	1,922	1,077	99
Other expense, net	(1,861)	(2,663)	(396)
(Loss) income before income taxes	(7,506)	2,487	(22,493)
Income tax expense	(4,036)	(4,023)	(4,781)
Net loss	\$ (11,542)	\$ (1,536)	\$ (27,274)
Basic net loss per share	\$ (0.82)	\$ (0.11)	\$ (1.96)
Diluted net loss per share	\$ (0.82)	\$ (0.11)	\$ (1.96)
Weighted average number of shares outstanding:			
Basic	14,153	14,031	13,916
Diluted	14,153	14,031	13,916

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

Surmodics, Inc. and Subsidiaries
Consolidated Statements of Comprehensive (Loss) Income
For the Fiscal Year Ended September 30,

<i>(In thousands)</i>	2024	2023	2022
Net loss	\$ (11,542)	\$ (1,536)	\$ (27,274)
Other comprehensive income (loss):			
Derivative instruments:			
Unrealized net (loss) gain	(611)	260	—
Net gain reclassified to earnings	(245)	(77)	—
Net changes related to available-for-sale securities, net of tax	6	(6)	(1)
Foreign currency translation adjustments	3,483	4,938	(11,600)
Other comprehensive income (loss)	2,633	5,115	(11,601)
Comprehensive (loss) income	<u>\$ (8,909)</u>	<u>\$ 3,579</u>	<u>\$ (38,875)</u>

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

Surmodics, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
For the Fiscal Years Ended September 30, 2024, 2023 and 2022

<i>(In thousands)</i>	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at September 30, 2021	13,899	\$ 695	\$ 21,598	\$ 1,727	\$ 116,065	\$ 140,085
Net loss	—	—	—	—	(27,274)	(27,274)
Other comprehensive loss	—	—	—	(11,601)	—	(11,601)
Issuance of common stock	124	6	826	—	—	832
Common stock options exercised, net	27	1	413	—	—	414
Purchase of common stock to pay employee taxes	(21)	(1)	(1,120)	—	—	(1,121)
Stock-based compensation	—	—	7,057	—	—	7,057
Balance at September 30, 2022	14,029	701	28,774	(9,874)	88,791	108,392
Net loss	—	—	—	—	(1,536)	(1,536)
Other comprehensive income	—	—	—	5,115	—	5,115
Issuance of common stock	133	7	843	—	—	850
Common stock options exercised, net	19	1	401	—	—	402
Purchase of common stock to pay employee taxes	(26)	(1)	(917)	—	—	(918)
Stock-based compensation	—	—	7,605	—	—	7,605
Balance at September 30, 2023	14,155	708	36,706	(4,759)	87,255	119,910
Net loss	—	—	—	—	(11,542)	(11,542)
Other comprehensive income	—	—	—	2,633	—	2,633
Issuance of common stock	165	8	852	—	—	860
Common stock options exercised, net	36	2	354	—	—	356
Purchase of common stock to pay employee taxes	(31)	(2)	(1,535)	—	—	(1,537)
Stock-based compensation	—	—	8,217	—	—	8,217
Balance at September 30, 2024	14,325	\$ 716	\$ 44,594	\$ (2,126)	\$ 75,713	\$ 118,897

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

Surmodics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Fiscal Year Ended September 30,

<i>(In thousands)</i>	2024	2023	2022
Operating Activities:			
Net loss	\$ (11,542)	\$ (1,536)	\$ (27,274)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	8,694	8,522	9,142
Stock-based compensation	8,217	7,605	7,057
Noncash lease expense	804	652	529
Amortization of debt issuance costs	303	365	46
Provision for credit losses	64	37	5
Contingent consideration (gain) expense	—	(829)	12
Deferred taxes	(320)	(181)	5,268
Other	(613)	115	268
Change in operating assets and liabilities:			
Accounts receivable and contract assets	(5,236)	(977)	(1,522)
Inventories	(328)	(3,020)	(5,060)
Prepays and other	4,902	—	(665)
Accounts payable	(232)	(183)	1,608
Accrued liabilities	(885)	(1,024)	132
Income taxes	1,579	3,438	(1,069)
Deferred revenue	(5,159)	(2,470)	(5,700)
Net cash provided by (used in) operating activities	<u>248</u>	<u>10,514</u>	<u>(17,223)</u>
Investing Activities:			
Purchases of property and equipment	(3,492)	(2,918)	(3,370)
Purchases of available-for-sale securities	(25,445)	(3,904)	—
Maturities of available-for-sale securities	26,000	—	9,600
Net cash (used in) provided by investing activities	<u>(2,937)</u>	<u>(6,822)</u>	<u>6,230</u>
Financing Activities:			
Payments on short-term borrowings	—	(10,000)	—
Proceeds from issuance of long-term debt	—	29,664	—
Payment of debt issuance costs	—	(614)	—
Issuance of common stock	1,216	1,252	1,246
Payments for taxes related to net share settlement of equity awards	(1,537)	(918)	(1,121)
Payments for acquisition of in-process research and development	(931)	(978)	(500)
Payments for acquisition-related deferred consideration	(1,698)	—	—
Net cash (used in) provided by financing activities	<u>(2,950)</u>	<u>18,406</u>	<u>(375)</u>
Effect of exchange rate changes on cash	335	323	(787)
Net change in cash and cash equivalents	<u>(5,304)</u>	<u>22,421</u>	<u>(12,155)</u>
Cash and Cash Equivalents:			
Beginning of year	41,419	18,998	31,153
End of year	<u>\$ 36,115</u>	<u>\$ 41,419</u>	<u>\$ 18,998</u>

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

Surmodics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows (Continued)
For the Fiscal Year Ended September 30,

<i>(In thousands)</i>	<u>2024</u>	<u>2023</u>	<u>2022</u>
Supplemental Information:			
Cash paid for income taxes	\$ 2,568	\$ 2,851	\$ 416
Cash paid for interest	3,045	2,919	415
Noncash financing and investing activities:			
Acquisition of property and equipment funded through accounts payable and accrued liabilities	94	116	70
Right-of-use assets obtained in exchange for new operating lease liabilities	845	—	1,725

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

Surmodics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

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.

On May 28, 2024, Surmodics entered into a Merger Agreement (the “Merger Agreement”) with BCE Parent, LLC, a Delaware limited liability company (“Parent”), and BCE Merger Sub, Inc., a Minnesota corporation and a wholly owned Subsidiary of Parent (“Merger Sub”), pursuant to which Surmodics will, subject to the terms and conditions thereof, be acquired by Parent for \$43.00 per share in cash through the merger of Merger Sub with and into the Company, with the Company as the surviving corporation and a wholly owned subsidiary of Parent. See Note 13 Merger Agreement for additional information.

Basis of Presentation and Principles of Consolidation

The 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.

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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Ultimate results could differ from those estimates.

2. Summary of Significant Accounting Policies and Supplemental Balance Sheet Information

Cash and Cash Equivalents

Cash and cash equivalents consist of financial instruments with maturities of three months or less at the Company’s acquisition date of the security. Cash is stated at cost, which approximates fair value. Cash equivalents are stated at fair value. Cash and cash equivalents may include money market instruments, certificates of deposit, repurchase agreements and commercial paper instruments.

Investments — Available-for-sale Securities

As of September 30, 2024 and 2023, investments in available-for-sale debt securities totaled \$4.0 million and \$3.9 million, respectively, on the consolidated balance sheets. As of September 30, 2024 and 2023, investments consisted of commercial paper and corporate bond securities, were classified as available-for-sale, and were reported at fair value. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in investment income, net within other expense. Realized gains and losses from the sales of debt securities, which are included in investment income, net, are determined using the specific identification method. Investment purchases are accounted for on the date the trade is executed, which may not be the same as the date the transaction is cash settled. Unrealized gains and losses, net of tax, are excluded from the consolidated statements of operations and reported on the consolidated statements of comprehensive (loss) income and also as a separate component of stockholders’ equity on the consolidated balance sheets. For investments in an unrealized loss position, we make the following assessments. If it is more likely than not we will sell the investment before recovery of its amortized cost basis, we write down the security’s amortized cost basis to fair value and reclassify the net unrealized loss from accumulated other comprehensive loss to investment income, net on the consolidated statements of operations. If the decline in fair value is deemed to be due to a credit loss, we recognize an allowance for the expected credit loss to reduce the cost basis to fair value, with a corresponding adjustment to investment income, net.

The amortized cost, unrealized holding gains and losses, and fair value of available-for-sale securities were as follows:

<i>(In thousands)</i>	September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper and corporate bonds	\$ 3,997	\$ —	\$ —	\$ 3,997
Available-for-sale securities	<u>\$ 3,997</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,997</u>

<i>(In thousands)</i>	September 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper and corporate bonds	\$ 3,936	\$ —	\$ (3)	\$ 3,933
Available-for-sale securities	<u>\$ 3,936</u>	<u>\$ —</u>	<u>\$ (3)</u>	<u>\$ 3,933</u>

There were no held-to-maturity debt securities as of September 30, 2024 and 2023. There were no realized gains or losses on sales of available-for-sale securities for fiscal 2024, 2023 or 2022.

Accounts Receivable

We grant credit to customers in the normal course of business and maintain an allowance for credit losses. The allowance for credit losses reflects the current estimate of credit losses expected to be incurred over the life of the accounts receivable. We consider various factors in establishing, monitoring and adjusting the allowance for credit losses including the aging of accounts and aging trends, the historical level of charge-offs, and specific exposures related to particular customers. We base our estimates of credit loss reserves on historical experience and adjust, as necessary, to reflect current conditions using reasonable and supportable forecasts not already reflected in the historical loss information.

Inventories

Inventories are principally stated at the lower of cost or net realizable value using the specific identification method and include direct labor, materials and overhead, with cost of product sales determined on a first-in, first-out basis. Inventories, net of reserves of \$2.6 million and \$1.8 million as of September 30, 2024 and 2023, respectively, consisted of the following components:

<i>(In thousands)</i>	September 30,	
	2024	2023
Raw materials	\$ 8,505	\$ 8,063
Work-in process	2,476	2,607
Finished products	4,187	4,169
Inventories	<u>\$ 15,168</u>	<u>\$ 14,839</u>

We regularly review inventory quantities, and when appropriate, record reserves for excess and obsolete inventory to reduce the balance of inventories, net on the consolidated balance sheets, with corresponding charges to product costs on the consolidated statements of operations. We write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements based on future demand and as compared to remaining shelf life. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product.

Prepays and Other Assets, Current

Prepays and other current assets consisted of the following:

<i>(In thousands)</i>	September 30,	
	2024	2023
Prepaid expenses	\$ 2,752	\$ 2,600
Irish research and development credits receivable	108	1,322
CARES Act employee retention credit receivable (1)	—	3,441
Prepays and other	<u>\$ 2,860</u>	<u>\$ 7,363</u>

- (1) As of September 30, 2023, this receivable consisted of anticipated reimbursement of personnel expenses, which were incurred in fiscal 2021 and fiscal 2020, as the result of our eligibility for the employee retention credit under the provisions of the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”). During fiscal 2024, we received payment for this receivable.

Property and Equipment

Property and equipment are stated at cost, less any impairment, and are depreciated using the straight-line method over the estimated useful lives of the assets. The Company recorded depreciation expense of \$4.9 million, \$4.7 million and \$4.7 million in fiscal 2024, 2023 and 2022, respectively.

The September 30, 2024 and 2023 balances in construction-in-progress include the cost of equipment and building improvements not yet placed in service. As assets are placed in service, construction-in-progress is transferred to the specific property and equipment categories and depreciated over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the term of the lease or the estimated useful life of the asset. Expenditures for maintenance and repairs and minor renewals and betterments that do not extend or improve the life of the respective assets are expensed as incurred.

Property and equipment consisted of the following components:

<i>(Dollars in thousands)</i>	Useful Life (Years)	September 30,	
		2024	2023
Land	N/A	\$ 4,416	\$ 4,413
Laboratory fixtures and equipment	3 to 10	34,670	33,120
Buildings and improvements	3 to 20	29,490	26,964
Leasehold improvements	5 to 10	6,499	6,499
Office furniture and equipment	3 to 10	10,207	9,561
Construction-in-progress		1,478	1,936
Less: Accumulated depreciation		(61,804)	(56,467)
Property and equipment, net		<u>\$ 24,956</u>	<u>\$ 26,026</u>

Intangible Assets

Intangible assets consisted of the following:

<i>(Dollars in thousands)</i>	September 30, 2024			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	9.3	\$ 11,870	\$ (10,844)	\$ 1,026
Developed technology	11.9	35,433	(14,222)	21,211
Patents and other	14.9	2,338	(1,586)	752
Total definite-lived intangible assets		49,641	(26,652)	22,989
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Intangible assets, net		<u>\$ 50,221</u>	<u>\$ (26,652)</u>	<u>\$ 23,569</u>

<i>(Dollars in thousands)</i>	September 30, 2023			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	9.3	\$ 11,260	\$ (9,435)	\$ 1,825
Developed technology	11.9	33,929	(11,048)	22,881
Patents and other	14.9	2,338	(1,418)	920
Total definite-lived intangible assets		47,527	(21,901)	25,626
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Intangible assets, net		<u>\$ 48,107</u>	<u>\$ (21,901)</u>	<u>\$ 26,206</u>

The Company recorded amortization expense of \$3.8 million, \$3.8 million and \$4.4 million in fiscal 2024, 2023 and 2022, respectively.

Based on the intangible assets in service as of September 30, 2024, estimated amortization expense for future fiscal years is as follows:

<i>(In thousands)</i>	
2025	\$ 3,820
2026	2,903
2027	2,648
2028	2,637
2029	2,637
Thereafter	8,344
Definite-lived intangible assets	<u>\$ 22,989</u>

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 exchange rates or other factors.

The Company defines in-process research and development (“IPR&D”) as the value of technology acquired for which the related projects have substance and are incomplete. IPR&D acquired in a business combination is recognized at fair value and is capitalized as an indefinite-lived intangible asset until completion or abandonment of the IPR&D project. Upon completion of the development project (generally when regulatory approval to market the product is obtained), an impairment assessment is performed prior to amortizing the asset over its estimated useful life. In cases where the IPR&D projects are abandoned, the related IPR&D assets are written off.

The Company performs its annual assessment of indefinite-lived assets for impairment annually as of July 1st of each fiscal year and whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. We test indefinite-lived intangible assets for impairment annually, or more frequently if events or changes in circumstances indicate that the assets may be impaired. Our annual impairment test may be completed through a qualitative assessment to determine if the fair value of the indefinite-lived intangible assets is more likely than not greater than the carrying amount. If we elect to bypass the qualitative assessment, or if a qualitative assessment indicates it is more likely than not that the estimated carrying value exceeds the fair value, we test for impairment using a quantitative process. Similar to the goodwill impairment assessment, the indefinite-lived assets impairment assessment requires the Company to make several estimates about fair value, most of which are based on projected future cash flows. For the annual impairment test of our indefinite-lived intangible assets in the fourth quarter of 2024, we elected to perform a qualitative assessment. This qualitative assessment indicated the fair value of our indefinite-lived intangible assets was more likely than not greater than the carrying amount. No impairment charges were recorded in fiscal 2024, 2023 and 2022.

Goodwill

Goodwill in the Medical Device reporting unit represents the gross value from the fiscal 2021 acquisition of Vetex Medical Limited (“Vetex”) and the fiscal 2016 acquisitions of Creagh Medical, Ltd. (“Creagh Medical”) and NorMedix, Inc. (“NorMedix”). Goodwill in the In Vitro Diagnostics reporting unit represents the gross value from the acquisition of BioFX Laboratories, Inc. in 2007.

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

<i>(In thousands)</i>	In Vitro Diagnostics	Medical Device	Total
Goodwill as of September 30, 2022	\$ 8,010	\$ 32,700	\$ 40,710
Foreign currency translation adjustment	—	2,236	2,236
Goodwill as of September 30, 2023	8,010	34,936	42,946
Foreign currency translation adjustment	—	1,694	1,694
Goodwill as of September 30, 2024	<u>\$ 8,010</u>	<u>\$ 36,630</u>	<u>\$ 44,640</u>

Goodwill represents the excess of the purchase price of an acquired business over the fair value assigned to the assets purchased and liabilities assumed. Goodwill is not amortized but is subject, at a minimum, to annual tests for impairment. The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change indicating that it is more likely than not that the fair value of a reporting unit is less than its carrying amount.

The Company's reporting units are the Medical Device and In Vitro Diagnostics reportable segments. To determine if goodwill is potentially impaired, we have the option to perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If we elect not to conduct the qualitative assessment or if indications of a potential impairment exist, the determination of whether an impairment has occurred requires the fair value of each reporting unit to be assessed by performing a quantitative assessment. Inherent in the determination of fair value of the reporting units are certain estimates and judgments, including the interpretation of current economic indicators and market valuations, as well as the Company's strategic plans with regard to its operations.

Under the qualitative assessment, we consider several factors, including the business enterprise value of the reporting unit from the last quantitative test and the excess of fair value over carrying value from this test, macroeconomic conditions, industry and market considerations, the recent and projected financial performance of the reporting unit, as well as other factors.

Under the quantitative assessment, we determine fair value at the reporting unit level based on a combination of an income approach and market approach. The income approach is based on estimated future cash flows, discounted at a rate that approximates the cost of capital of a market participant, while the market approach is based on sales and/or earnings multiples of similar companies. These approaches use significant estimates and assumptions, including projected future cash flows and the timing of those cash flows, discount rates reflecting risks inherent in future cash flows, perpetual growth rates, and determination of appropriate market comparables.

The Company performs its assessment of goodwill for impairment as of July 1st of each fiscal year. Goodwill was not impaired in either reporting unit based on the outcome of the fiscal 2024 annual impairment test, which utilized a qualitative assessment. No goodwill impairment charges were recorded in fiscal 2024, 2023 and 2022.

Other Assets, Noncurrent

Other noncurrent assets consisted of the following:

<i>(In thousands)</i>	September 30,	
	2024	2023
Operating lease right-of-use assets	\$ 3,028	\$ 2,987
Contract asset (1)	689	—
Other	376	877
Other assets, noncurrent	<u>\$ 4,093</u>	<u>\$ 3,864</u>

- (1) As of September 30, 2024, consisted of the noncurrent portion of the contract asset associated with estimated SurVeil™ DCB profit-sharing. See Revenue Recognition within this Note 2 for further disclosure.

Valuation of Long-lived Assets

The Company periodically evaluates whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of long-lived assets, such as property and equipment, right-of-use assets, and definite-lived intangible assets. If such events or circumstances were to indicate that the carrying amount of these assets may not be recoverable, the Company would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) were less than the carrying amount of the assets, the Company would recognize an impairment charge to reduce such assets to their fair value. In fiscal 2024, 2023 and 2022, no impairment charges were recorded related to the Company's long-lived assets.

Accrued Other Liabilities

Accrued other liabilities consisted of the following:

<i>(In thousands)</i>	September 30,	
	2024	2023
Accrued professional fees	\$ 563	\$ 178
Accrued clinical study expense	499	1,056
Accrued purchases	1,023	1,142
Operating lease liability, current portion	1,040	872
Deferred consideration (1)	—	2,661
Other	670	535
Accrued other liabilities	<u>\$ 3,795</u>	<u>\$ 6,444</u>

- (1) As of September 30, 2023, deferred consideration consisted of the present value of guaranteed payments to be made in connection with the fiscal 2021 Vetex acquisition and with an asset acquisition in fiscal 2019 (Note 11).

Other Long-term Liabilities

Other long-term liabilities consisted of the following:

<i>(In thousands)</i>	September 30,	
	2024	2023
Unrecognized tax benefits (1)	\$ 3,176	\$ 3,332
Operating lease liabilities, less current portion (2)	2,648	2,974
Deferred consideration (3)	1,661	1,629
Other	298	125
Other long-term liabilities	<u>\$ 7,783</u>	<u>\$ 8,060</u>

- (1) Unrecognized tax benefits (Note 9) included accrued interest and penalties, if applicable.
- (2) 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.
- (3) Deferred consideration consisted of the present value of a guaranteed payment to be made in connection with the fiscal 2021 Vetex acquisition (Note 11).

Revenue Recognition

Revenue is recognized when control of the promised goods or services is transferred to our customers in an amount that reflects the consideration we expect to be entitled to receive in exchange for those goods or services. The Company primarily sells or licenses its products, technologies and services to other medical device and diagnostics companies. Revenue is recorded net of taxes collected from customers, and taxes collected are recorded as current liabilities until remitted to the relevant government authority. The amount of foreign taxes imposed on specific revenue producing transactions that is the responsibility of the Company is expensed as incurred and reported in income tax expense on the consolidated statements of operations. For contracts that have an original duration of one year or less, the Company uses the practical expedient applicable to such contracts and does not adjust the transaction price for the time value of money.

Performance Obligations

We derive our revenue from three primary sources:

Product Sales	Royalties and License Fees	Research, Development and Other
IVD chemical and biological components, including protein stabilizers, surface coatings, substrates and antigens to the diagnostic and biomedical research markets (IVD segment)	Performance coating royalties and license fees from licensing of our proprietary performance coating technologies to medical device manufacturers (Medical Device segment)	Commercial development feasibility services and contract coating services (Medical Device segment)
Vascular intervention medical devices and related products to original equipment manufacturer suppliers and distributors, as well as directly to healthcare providers (Medical Device segment)	SurVeil™ DCB license fees associated with the Abbott Agreement (Medical Device segment)	Commercial development services (IVD segment)
Performance coating reagents, the chemicals used in performance coatings by licensees (Medical Device segment)		

The Company recognizes revenue when control is transferred to the customer. The transfer of control varies by revenue classification and is described below. If a contract contains more than one distinct performance obligation, the transaction price is allocated to each performance obligation based on relative standalone selling price.

Product Sales. Revenue from product sales is recognized at the point in time control of the products is transferred, generally upon shipment based upon the standard contract terms. Shipping and handling activities are considered to be fulfillment activities rather than promised services and are not, therefore, considered to be separate performance obligations. The amount of revenue recognized is based on the transaction price, which generally represents the invoiced amount, net of administrative fees where applicable. The Company's sales terms provide no right of return outside of a standard warranty policy, and returns are generally not significant. Payment terms for product sales are generally set at 30-45 days after shipment.

Royalties. Royalties revenue consists of sales-based and recurring minimum royalties earned under licenses of our performance coating technologies. Performance obligations under these licenses, which consist of the right to use the Company's proprietary technology, are satisfied at a point in time corresponding with delivery of the underlying technology rights to the customer, which is generally upon transfer of the licensed technology to the customer. Sales-based royalties revenue represents variable consideration under the license agreements and is recognized in the period a customer sells products incorporating the Company's licensed technologies. Our customers generally report sales subject to royalties to us in the quarter after those sales occur. The Company estimates sales-based royalties revenue earned but unpaid at each reporting period using the expected value method based on historical sales information, adjusted for known changes such as product launches and patent expirations. The Company also considers macroeconomic factors affecting the medical device market. The Company's license arrangements also often provide for recurring fees (minimum royalties), which the Company recognizes at the later of the satisfaction of the underlying performance obligation or upon renewal of the contract, which generally occurs on a quarterly basis. Sales-based and minimum royalties are generally due within 45 days after the end of each quarter.

License Fees. For distinct license performance obligations, upfront license fees are recognized when the Company satisfies the underlying performance obligation. This generally occurs upon transfer of the right to use the Company's licensed technology to the customer, with the exception of the license of the Company's *SurVeil* drug-coated balloon (the "*SurVeil* DCB") disclosed below. Certain license arrangements include contingent milestone payments, which are due following achievement by our customers of specified sales or regulatory milestones. Contingent milestone payment terms vary by contract. The Company has generally fulfilled its performance obligation prior to achievement of these milestones. However, because of the uncertainty of the milestone achievement, and/or the dependence on sales of our customers, variable consideration for contingent milestones is fully constrained and excluded from the contract price until the milestone is achieved by our customer, to the extent collectability is reasonably certain.

Research and Development. The Company performs research and development ("R&D") activities as a service to customers, which are typically charged to customers on a time-and-materials basis. Generally, revenue for R&D services is recorded over time as the services are provided to the customer in the amount to which the Company has the right to invoice. These services are generally charged to the customer as they are provided. Payment terms for R&D services are generally set at 30-45 days.

SurVeil DCB Revenue Recognition

On February 26, 2018, the Company entered into an agreement with Abbott Vascular, Inc. (“Abbott”) with respect to one of the device products in our Medical Device reportable segment, the *SurVeil* DCB for treatment of the superficial femoral artery (the “Abbott Agreement”). In June 2023, the *SurVeil* DCB received U.S. Food and Drug Administration (“FDA”) premarket approval (“PMA”) and may now be marketed and sold in the U.S. by Abbott. To account for the Abbott Agreement, the Company applied the guidance in ASC Topic 808 (Collaborative Arrangements) as the parties are active participants and are exposed to significant risks and rewards dependent on commercial success of the collaborative activity. The performance obligations and corresponding revenue recognized under the Abbott Agreement included (i) *SurVeil* DCB license fee revenue recognized in fiscal 2024, 2023 and 2022 within royalties and license fees on the consolidated statements of operations; and (ii) beginning in fiscal 2024, product sales associated with shipment of commercial units of the *SurVeil* DCB to Abbott.

SurVeil DCB License Fee Revenue. As of September 30, 2024, the Company has received upfront and milestone payments totaling \$87.8 million under the Abbott Agreement, and there are no remaining contingent milestone payments under the Abbott Agreement. The associated performance obligation identified in the Abbott Agreement includes delivery of our licensed technology and completion of research and development activities, primarily clinical trial activities (together, “R&D and Clinical Activities”). These promises are not distinct performance obligations because the product necessary for completion of the R&D and Clinical Activities is currently only able to be manufactured by the Company due to the exclusive proprietary know-how and certain regulatory requirements associated with the manufacture of the product. The customer, Abbott, simultaneously receives and consumes the benefits of the R&D and Clinical Activities as study data are generated to support regulatory approval submissions. Control is effectively transferred over time as we complete the TRANSCEND clinical study of the *SurVeil* DCB and related regulatory activities. License fee revenue related to this contract is recognized using the cost-to-cost method which measures progress based on costs incurred to date relative to the expected total cost of the services, as the Company believes this represents a faithful depiction of the satisfaction of its performance obligation. Use of the cost-to-cost method requires significant estimates, including the total cost of the TRANSCEND study, which is expected to be completed over the next two years. Revenue is recorded based on the cost-to-cost completion estimate relative to the transaction price, which is equal to the total upfront fee plus the expected value of the clinical and regulatory milestones.

Revenue from the upfront and milestone payments, once the underlying contingencies are achieved, is recognized within royalties and license fees on the consolidated statements of operations as the clinical and regulatory activities are performed on a proportional performance basis. Performance is measured based on actual costs incurred relative to the expected total cost of the underlying activities, most notably the completion of the TRANSCEND clinical trial. A significant component of the cost of this trial is the cost of the Company’s outsourced clinical trial clinical research organization (“CRO”) consultants, which is estimated based on executed statements of work, project budgets, and patient enrollment timing, among other factors. A significant change to the Company’s estimate of the costs to complete the TRANSCEND clinical trial could have a material effect on the Company’s results of operations. Significant judgment is used to estimate total revenue and cost at completion for this contract.

SurVeil DCB Product Sales. Under the Abbott Agreement, we supply commercial units of the *SurVeil* DCB to Abbott, and Abbott has exclusive worldwide distribution rights. During the first quarter of fiscal 2024, we commenced shipment of commercial units of the *SurVeil* DCB to Abbott. We recognize revenue from the sale of commercial units of the *SurVeil* DCB to Abbott at the time of shipment in product sales on the consolidated statements of operations. The amount of *SurVeil* DCB product sales revenue recognized includes (i) the contractual transfer price per unit and (ii) an estimate of Surmodics’ share of net profits resulting from product sales by Abbott to third parties pursuant to the Abbott Agreement (“estimated *SurVeil* DCB profit-sharing”). On a quarterly basis, Abbott (i) reports to us its third-party sales of the *SurVeil* DCB the quarter after those sales occur, which may occur within two years following shipment based on the product’s current shelf life; and (ii) reports to us and pays the actual amount of profit-sharing. Estimated *SurVeil* DCB profit-sharing represents variable consideration and is recorded in contract assets, current and other assets, noncurrent on the consolidated balance sheets. We estimate variable consideration as the most-likely amount to which we expect to be entitled, and we include estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue will not occur when the uncertainty associated with the variable consideration is resolved. Significant judgment is required in estimating the amount of variable consideration to recognize when assessing factors outside of Surmodics’ influence, such as limited availability of third-party information, expected duration of time until resolution, and limited relevant past experience.

See Note 4 Collaborative Arrangement for further disclosures related to the Abbott Agreement.

Contract Assets, Deferred Revenue and Remaining Performance Obligations

Contract assets consist of (i) sales-based and minimum performance coating royalties revenue earned for which unconditional right to payment does not exist as of the balance sheet date and (ii) sales-based profit-sharing earned, but not collected, related to a collaborative arrangement as discussed above under “*SurVeil* DCB Product Sales.” Contract assets associated with performance coating royalties and license fees consist of estimated sales-based royalties earned, but not yet reported by the Company’s customers, minimum royalties on non-cancellable contracts, and contingent milestones earned, but not yet billable based on the terms of the contract. See Note 3 Revenue for further contract asset disclosures.

The Company records a contract liability, or deferred revenue, when there is an obligation to provide a product or service to the customer, and payment is received or due in advance of performance, or when payment is received for a period outside the contract term. See Note 3 Revenue for further deferred revenue disclosures.

Remaining performance obligations include deferred revenue and amounts the Company expects to receive for goods and services that have not yet been delivered or provided under existing, noncancellable contracts. For contracts that have an original duration of one year or less, the Company has elected the practical expedient applicable to such contracts and does not disclose the transaction price for remaining performance obligations at the end of each reporting period or the expecting timing of recognition of related revenue. See Note 4 Collaborative Arrangement for further performance obligation disclosures.

Product Costs

Product costs consist primarily of the cost of raw materials, components, direct labor and manufacturing overhead. Overhead costs include the cost of quality assurance and control, materials procurement, inventory control, facilities, and manufacturing supervision and management, including stock-based compensation. Product costs also includes depreciation expense for production equipment and facilities, charges for excess and obsolete inventory, and certain direct costs such as shipping and handling costs.

Leases

The Company leases facilities for research, office, manufacturing and warehousing. The Company determines whether a contract is a lease or contains a lease at inception date. Upon commencement, the Company recognizes a right-of-use asset and lease liability based on the net present value of the future minimum lease payments over the lease term at the commencement date. The net present value of future minimum lease payments recorded upon lease commencement is reduced by the discounted value of any leasehold improvement incentives payable to the Company considered to be in-substance fixed payments. The unamortized balance of leasehold improvement incentives in the form of tenant allowances represents the primary difference between the balance of the right-of-use assets and operating lease liabilities. As the Company’s leases typically do not provide an implicit rate, the Company’s lease liabilities are measured on a discounted basis using the Company’s incremental borrowing rate. Lease terms used in the recognition of right-of-use assets and lease liabilities include only options to extend the lease that are reasonably certain to be exercised. The consolidated balance sheets do not include recognized assets or liabilities for leases that, at the commencement date, have a term of twelve months or less and do not include an option to purchase the underlying asset that is reasonably certain to be exercised. The Company recognizes such leases on the consolidated statements of operations on a straight-line basis over the lease term.

The Company’s leases include one or more options to renew and extend the lease term at the Company’s discretion. These renewal options are not included in right-of-use assets and lease liabilities as they are not reasonably certain of exercise. The Company regularly evaluates renewal options, and when they are reasonably certain to be exercised, the renewal period is included in the lease term.

As of September 30, 2024, operating lease maturities were as follows:

<i>(In thousands)</i>	
2025	\$ 1,214
2026	1,132
2027	1,135
2028	574
2029	—
Total expected operating lease payments	4,055
Less: Imputed interest	(367)
Total operating lease liabilities	<u>\$ 3,688</u>

Operating lease cost was \$1.6 million, \$1.4 million and \$1.1 million for fiscal 2024, 2023 and 2022, respectively. Cash paid for operating lease liabilities approximated operating lease cost for fiscal 2024, 2023 and 2022. As of September 30, 2024, the weighted average remaining lease term for operating leases was 3.4 years, and the weighted average discount rate used to determine operating lease liabilities was 3.9%.

Stock-based Compensation

We measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. Share-based payments are expensed based on their grant-date fair values on a straight-line basis over the requisite service period of the total award, less estimated forfeitures based on historical experience. Shares awarded under the Company's stock-based compensation plans, with the exception of restricted stock awards, are not considered issued or outstanding common stock of the Company until they vest and the shares are released. New awards and forfeitures of unvested restricted stock result in an increase (decrease), respectively, in common stock issued and outstanding.

Research and Development

R&D expenses include costs associated with the design, development, testing, enhancement and regulatory approval of the Company's products. R&D expenses include employee compensation (including stock-based compensation), internal and external costs associated with our regulatory compliance and quality assurance functions, the costs of product used in development and clinical trials, consulting expenses, and facilities overhead. The Company also incurs significant R&D expenses to operate clinical trials. R&D costs are expensed as incurred.

Certain R&D costs are related to customer contracts, and the related revenue is recognized as described in "Revenue Recognition" in this Note 2. Costs associated with customer-related R&D include specific project direct labor and materials expenses, as well as an allocation of overhead costs based on direct labor costs.

Clinical Trial Costs. The Company sponsors clinical trials intended to obtain the necessary clinical data required to obtain approval from various regulatory agencies to market medical devices developed by the Company. Costs associated with clinical trials include trial design and management expenses, clinical site reimbursements and third-party fees, among other costs. The Company's clinical trials may be administered by third-party CROs. These CROs generally bill monthly for certain services performed, as well as upon achievement of certain milestones. The Company monitors patient enrollment, the progress of clinical studies, and related activities through internal reviews of data reported to the Company by the CROs and correspondence with the CROs. We periodically evaluate our estimates to determine if adjustments are necessary or appropriate based on information received.

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 (i) amounts 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 consolidated balance sheets. See Note 7 Derivative Financial Instruments for further disclosures.

Litigation

From time to time, the Company may become involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. The outcomes of these legal actions are not within the Company's complete control and may not be known for prolonged periods of time. In some actions, the claimants may seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, which if granted, could require significant expenditures or result in lost revenue. The Company records a liability on the consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate, the minimum amount of the range is accrued. If a loss is possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

Income Taxes

We record a tax (expense) benefit for the anticipated tax consequences of the reported results of operations. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable (loss) income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in earnings in the period that includes the enactment date of such change.

Deferred tax assets represent amounts available to reduce income taxes payable on taxable income in future years. Such assets arise from net operating losses and tax credits and are primarily a result of temporary differences between the financial reporting and tax bases of assets and liabilities. We evaluate the recoverability of deferred tax assets by assessing all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance for deferred tax assets is needed. A valuation allowance is established if it is more likely than not (defined as a likelihood of more than 50%) that all or a portion of deferred tax assets will not be realized. The determination of whether a valuation allowance should be established, as well as the amount of such allowance, requires significant judgment and estimates, including estimates of future earnings.

In evaluating the realizability of our net deferred tax assets, we perform an assessment each reporting period of both positive and negative evidence, including (i) the existence of three-year cumulative U.S. pre-tax (losses) income adjusted for permanent adjustments, (ii) our forecast of future earnings, and (iii) future reversal of taxable temporary differences and carryforwards. We apply judgment to consider the relative impact of negative and positive evidence, and the weight given to negative and positive evidence is commensurate with the extent to which such evidence can be objectively verified. Objective historical evidence, such as cumulative three-year pre-tax income (losses) adjusted for permanent adjustments, is given greater weight than subjective positive evidence such as forecasts of future earnings. The more objective negative evidence that exists limits our ability to consider other, potentially positive, subjective evidence, such as our future earnings projections. 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 adjustments to the valuation allowance in future reporting periods that could have a material effect on our results of operations.

Net Loss Per Share Data

Basic net loss (income) per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss (income) per common share is computed by dividing net loss (income) 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 following table presents the denominator for the computation of diluted weighted average shares outstanding:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Basic weighted average shares outstanding	14,153	14,031	13,916
Dilutive effect of outstanding stock options, non-vested restricted stock, and non-vested restricted stock units	—	—	—
Diluted weighted average shares outstanding	<u>14,153</u>	<u>14,031</u>	<u>13,916</u>

The calculation of diluted loss per share excluded 0.1 million in weighted-average shares for each of fiscal 2024, 2023 and 2022, as their effect was anti-dilutive.

Repurchase of Common Stock

Shares are repurchased from time to time to support the Company's stock-based compensation programs and to return capital to shareholders, and depend upon many factors, including the Company's results of operations, financial condition, capital requirements and contractual restrictions. The Company accounts for repurchases of common stock using the par value method.

On November 6, 2015, and on November 5, 2014, the Company’s Board of Directors authorized the repurchase of up to \$20.0 million and \$30.0 million, respectively, of the Company’s outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of such methods. The authorizations have no fixed expiration date. As of September 30, 2024, \$25.3 million remained available to the Company for the purchase of its common stock under outstanding authorizations. However, both the Merger Agreement and our credit agreement in effect at September 30, 2024 restrict us from repurchasing outstanding shares of the Company’s common stock.

Business Combinations

For acquisitions accounted for as business combinations, we record assets and liabilities acquired at their respective fair values as of the acquisition date. Contingent consideration is recognized at fair value as of the acquisition date, and changes in fair value are recognized in earnings until settlement. Acquisition-related transaction costs are expensed as incurred.

Currency Translation

The Company’s reporting currency is the U.S. dollar. Assets and liabilities of non-U.S. dollar functional currency subsidiaries are translated into U.S. dollars at the period-end exchange rates, and revenue and expenses are translated at the average quarterly exchange rates during the period. The net effect of these translation adjustments on the consolidated financial statements is recorded as a foreign currency translation adjustment, a component of accumulated other comprehensive loss on the consolidated balance sheets. Realized foreign currency transaction gains and losses are included in other expense, net on the consolidated statements of operations.

New Accounting Pronouncements

Not Yet Adopted

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2023-07, *Segment Reporting: Improvements to Reportable Segment Disclosures*. This guidance requires disclosure of incremental segment information on an annual and interim basis. This amendment is effective for our fiscal year ending September 30, 2025 and interim periods within our fiscal year ending September 30, 2026. We are currently assessing the impact of this guidance on our disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes: Improvements to Income Tax Disclosures*. This guidance requires consistent categories and greater disaggregation of information in the rate reconciliation and disclosures of income taxes paid by jurisdiction. This amendment is effective for our fiscal year ending September 30, 2026 and interim periods within our fiscal year ending September 30, 2027. We are currently assessing the impact of this guidance on our disclosures.

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

3. Revenue

The following is a disaggregation of revenue within each reportable segment:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Medical Device			
Product sales	\$ 45,620	\$ 34,126	\$ 27,930
Royalties & license fees – performance coatings	37,408	32,812	30,547
License fees – <i>SurVeil</i> DCB	5,080	29,586	5,701
Research, development and other	9,400	9,259	8,211
Medical Device revenue	97,508	105,783	72,389
In Vitro Diagnostics			
Product sales	27,970	26,488	26,691
Research, development and other	600	313	871
In Vitro Diagnostics revenue	28,570	26,801	27,562
Total Revenue	\$ 126,078	\$ 132,584	\$ 99,951

Contract assets reported in contract assets, current and other assets, noncurrent on the consolidated balance sheets consisted of the following:

<i>(In thousands)</i>	September 30,	
	2024	2023
Contract assets:		
Performance coating royalties and license fees	\$ 8,534	\$ 7,796
<i>SurVeil</i> DCB profit-sharing	1,338	—
Contract assets, current	9,872	7,796
<i>SurVeil</i> DCB profit-sharing, noncurrent	689	—
Total contract assets	\$ 10,561	\$ 7,796

Fluctuations in the balance of contract assets result primarily from (i) fluctuations in the sales volume of performance coating royalties and license fees earned, but not collected, at each balance sheet date due to payment timing and contractual changes in the normal course of business; and (ii) starting in fiscal 2024, sales-based profit-sharing earned, but not collected, related to a collaborative arrangement for our *SurVeil* DCB products (Note 4).

Deferred revenue totaled \$1.6 million and \$6.8 million as of September 30, 2024 and 2023, respectively, on the consolidated balance sheets and was primarily related to a collaborative arrangement (Note 4). For fiscal 2024, 2023 and 2022, the total amount of revenue recognized that was included in the respective beginning of fiscal year balances of deferred revenue on the consolidated balance sheets totaled \$5.3 million, \$4.6 million and \$5.7 million, respectively.

Revenue from customers that equaled or exceeded 10% of total revenue was as follows:

	Fiscal Year		
	2024	2023	2022
Abbott	16%	27%	11%
Medtronic	12%	10%	13%

Revenue by geographic region was as follows:

	Fiscal Year		
	2024	2023	2022
Domestic	83%	82%	74%
Foreign	17%	18%	26%

4. Collaborative Arrangement

On February 26, 2018, the Company entered into the Abbott Agreement with respect to one of the device products in our Medical Device reportable segment, the *SurVeil* DCB, for treatment of the superficial femoral artery. In June 2023, the *SurVeil* DCB received PMA from the FDA and may now be marketed and sold in the U.S. by Abbott.

SurVeil DCB License Fees

Under the Abbott Agreement, Surmodics is responsible for conducting all necessary clinical trials, including completion of the ongoing, five-year TRANSCEND pivotal clinical trial of the *SurVeil* DCB. The Company has received payments totaling \$87.8 million for achievement of clinical and regulatory milestones under the Abbott Agreement, which consisted of the following: (i) a \$25 million upfront fee in fiscal 2018, (ii) a \$10 million milestone payment in fiscal 2019, (iii) a \$10.8 million milestone payment in fiscal 2020, (iv) a \$15 million milestone payment in fiscal 2021, and (v) a \$27 million milestone payment in fiscal 2023 upon receipt of PMA for the *SurVeil* DCB from the FDA. There are no remaining contingent or other milestone payments under the Abbott Agreement.

License fee revenue on milestone payments received under the Abbott Agreement is recognized using the cost-to-cost method based on total costs incurred to date relative to total expected costs for the TRANSCEND pivotal clinical trial, which is expected to be completed fiscal 2025. See Note 3 Revenue for *SurVeil* DCB license fee revenue recognized in our Medical Device reportable segment.

As of September 30, 2024, deferred revenue on the consolidated balance sheets included \$1.5 million from upfront and milestone payments received under the Abbott Agreement. This represented the Company's remaining performance obligations and is expected to be recognized as revenue over less than the next one year as services, principally the TRANSCEND clinical trial, are completed.

SurVeil DCB Product Sales

Under the Abbott Agreement, we supply commercial units of the *SurVeil* DCB to Abbott, and Abbott has exclusive worldwide distribution rights. During the first quarter of fiscal 2024, we commenced shipment of commercial units of the *SurVeil* DCB to Abbott. We recognize revenue from the sale of commercial units of the *SurVeil* DCB to Abbott at the time of shipment in product sales on the consolidated statements of operations. The amount of *SurVeil* DCB product sales revenue recognized includes (i) the contractual transfer price per unit and (ii) an estimate of Surmodics' share of net profits resulting from product sales by Abbott to third parties pursuant to the Abbott Agreement ("estimated *SurVeil* DCB profit-sharing").

See Note 2 for further information regarding *SurVeil* DCB license fee revenue recognition and estimated *SurVeil* DCB profit-sharing revenue recognition.

5. Fair Value Measurements

In determining the fair value of financial assets and liabilities, we utilize market data or other assumptions that we believe market participants would use in pricing the asset or liability in the principal or most advantageous market and adjust for non-performance and/or other risk associated with the company as well as counterparties, as appropriate. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 — Quoted (unadjusted) prices in active markets for identical assets or liabilities.

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

Level 3 — Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those with fair value measurements that are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation. In valuing Level 3 assets and liabilities, we are required to maximize the use of quoted market prices and minimize the use of unobservable inputs.

The hierarchy gives the highest priority to Level 1, as this level provides the most reliable measure of fair value, while giving the lowest priority to Level 3.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

	September 30, 2024			Total Fair Value
	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<i>(In thousands)</i>				
Assets				
Cash equivalents (1)	\$ —	\$ 29,334	\$ —	\$ 29,334
Available-for-sale securities (1)	—	3,997	—	3,997
Total assets	<u>\$ —</u>	<u>\$ 33,331</u>	<u>\$ —</u>	<u>\$ 33,331</u>
Liabilities				
Interest rate swap (2)	\$ —	\$ 673	—	\$ 673
Total liabilities	<u>\$ —</u>	<u>\$ 673</u>	<u>\$ —</u>	<u>\$ 673</u>

September 30, 2023

<i>(In thousands)</i>	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)	\$ —	\$ 36,255	\$ —	\$ 36,255
Available-for-sale securities (1)	—	3,933	—	3,933
Interest rate swap (2)	—	183	—	183
Total assets	\$ —	\$ 40,371	\$ —	\$ 40,371

- (1) Fair value of cash equivalents (money market funds) and available-for-sale securities (commercial paper and corporate bond securities) was based on quoted vendor prices and broker pricing where all significant inputs were observable.
- (2) Fair value of interest rate swap was based on forward-looking, one-month term secured overnight financing rate (“Term SOFR”) spot rates and interest rate curves (Note 7).

Assets and Liabilities Measured at Fair Value on a Non-recurring Basis

We measure certain assets at fair value on a non-recurring basis, primarily goodwill, intangible assets, and long-lived assets. These assets were initially measured and recognized at amounts equal to the fair value determined as of the date of acquisition or purchase and are subject to changes in value only for foreign currency translation and impairment. See Note 2 for additional information on impairment assessments and related Level 3 inputs for goodwill, indefinite-lived intangible assets and long-lived assets.

Assets and Liabilities Not Measured at Fair Value

Certain financial instruments are not measured at fair value but are recorded at carrying amounts approximating fair value based on their short-term nature. The carrying value of cash, accounts receivable, accounts payable and accrued liabilities approximated fair value as of September 30, 2024 and 2023.

6. Debt

Debt consisted of the following:

<i>(In thousands)</i>	September 30,	
	2024	2023
Revolving Credit Facility, Term SOFR + 3.00%, maturing October 1, 2027	\$ 5,000	\$ 5,000
Tranche 1 Term Loans, Term SOFR +5.75%, maturing October 1, 2027	25,000	25,000
Long-term debt, gross	30,000	30,000
Less: Unamortized debt issuance costs	(446)	(595)
Long-term debt, net	<u>\$ 29,554</u>	<u>\$ 29,405</u>

MidCap Revolving Credit Facility and Term Loans

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 a preexisting revolving credit facility with Bridgewater Bank. The Company used 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 1.0% of the prepaid principal amount. 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 1.0% of the terminated commitment amount. 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 consolidated statements of operations.

7. Derivative Financial Instruments

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 September 30, 2024. 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 consolidated balance sheets. The unrealized gains (losses) 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 gains (losses) will be reclassified into interest expense on the 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 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 consolidated statements of cash flows.

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

<i>(In thousands)</i>	Asset (Liability)						Balance Sheet Location
	Gross Recognized Amount	Gross Offset Amount	Net Amount Presented	Cash Collateral Receivable	Net Amount Reported		
September 30, 2024							
Interest rate swap	\$ (673)	\$ —	\$ (673)	\$ 625	\$ (48)		Other long-term liabilities
September 30, 2023							
Interest rate swap	\$ 183	\$ —	\$ 183	\$ —	\$ 183		Other assets, noncurrent

The pre-tax amounts recognized in AOCL on the interest rate swap were as follows:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Beginning unrealized net gain in AOCL	\$ 183	\$ —	\$ —
Net (loss) gain recognized in other comprehensive income (loss)	(611)	260	—
Reclassification of net gain to interest expense	(245)	(77)	—
Ending unrealized net (loss) gain in AOCL	\$ (673)	\$ 183	\$ —

8. Stock-based Compensation Plans

The Company has stock-based compensation plans under which it grants stock options, restricted stock awards, restricted stock units and deferred stock units. Stock-based compensation expense was reported as follows on the consolidated statements of operations:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Product costs	\$ 282	\$ 279	\$ 234
Research and development	1,517	1,417	1,424
Selling, general and administrative	6,418	5,909	5,399
Total stock-based compensation expense	<u>\$ 8,217</u>	<u>\$ 7,605</u>	<u>\$ 7,057</u>

As of September 30, 2024, approximately \$11.1 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.2 years.

As of September 30, 2024, under the amended 2019 Equity Incentive Plan ("2019 Plan"), the Company is authorized to issue 2,340,000 shares, plus the number of shares pursuant to any awards granted under the 2009 Equity Incentive Plan ("2009 Plan") that were outstanding on the effective date of the 2019 Plan that expire, are cancelled or forfeited, or are settled for cash. As of September 30, 2024, there were approximately 481,000 shares available for future equity awards under the 2019 Plan, including stock options, restricted stock, restricted stock units and deferred stock units.

Stock Option Awards

The Company grants non-qualified stock options at fair market value on the grant date to certain key employees and members of the Board. The Company uses the Black-Scholes option pricing model to determine the fair value of stock options as of the date of each grant. Weighted average stock option fair value assumptions and the weighted average grant date fair value of stock options granted were as follows:

	Fiscal Year		
	2024	2023	2022
Stock option fair value assumptions:			
Risk-free interest rate	4.10%	3.76%	1.49%
Expected life (years)	4.8	4.7	4.6
Expected volatility	49%	45%	43%
Dividend yield	— %	— %	— %
Weighted average grant date fair value of stock options granted	\$ 15.69	\$ 15.03	\$ 15.96

The risk-free interest rate assumption is based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the awards. The expected life of options granted is determined based on the Company's experience. Expected volatility is based on the Company's stock price movement over a period approximating the expected term. Based on management's judgment, dividend yields are expected to be zero for the expected life of the options.

With respect to members of the Board, non-qualified stock options generally become exercisable on a monthly pro-rata basis within the one-year period following the date of grant. With respect to employees, non-qualified stock options generally become exercisable at a 25% rate on each of the first four anniversaries following the grant date. Non-qualified stock options generally expire in seven years or upon, or shortly after, termination of employment or service as a Board member. The stock-based compensation expense table above includes stock option expenses recognized related to these awards, which totaled \$4.0 million, \$3.7 million and \$3.4 million in fiscal 2024, 2023 and 2022, respectively.

As of September 30, 2024, the aggregate intrinsic value of the option shares outstanding was \$3.3 million, and the aggregate intrinsic value of option shares exercisable was \$1.0 million. As of September 30, 2024, the weighted average remaining contractual life of options outstanding and options exercisable was 4.0 years and 3.0 years, respectively. The total pre-tax intrinsic value of options exercised was \$1.5 million, \$0.3 million and \$1.0 million in fiscal 2024, 2023 and 2022, respectively. The intrinsic value represents the difference between the exercise price and the fair market value of the Company's common stock on the last day of the respective fiscal year end.

Stock option activity was as follows:

<i>(In thousands, except per share data)</i>	Number of Shares	Weighted Average Exercise Price
Options outstanding at September 30, 2021	922	\$ 39.39
Granted	342	42.10
Exercised	(45)	21.24
Forfeited and expired	(58)	43.99
Options outstanding at September 30, 2022	1,161	40.66
Granted	311	34.73
Exercised	(20)	21.50
Forfeited and expired	(90)	41.77
Options outstanding at September 30, 2023	1,362	39.52
Granted	283	33.39
Exercised	(195)	30.56
Forfeited and expired	(26)	38.75
Options outstanding at September 30, 2024	1,424	39.54
Options vested and exercisable at September 30, 2024	770	\$ 42.33

Restricted Stock Awards

The Company has entered into restricted stock agreements with certain key employees covering the issuance of common stock ("Restricted Stock"). Restricted Stock generally vests at a 33% rate on each of the first three anniversaries following the grant date. Restricted Stock is released to employees if they are employed by the Company at the end of the vesting period. Restricted Stock is valued based on the market value of the shares as of the date of grant with the value allocated to expense evenly over the vesting period. The stock-based compensation expense table above includes Restricted Stock expenses recognized related to these awards, which totaled \$3.4 million, \$3.1 million and \$2.7 million in fiscal 2024, 2023 and 2022, respectively.

Restricted Stock activity was as follows:

<i>(In thousands, except per share data)</i>	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock awards at September 30, 2021	119	\$ 41.14
Granted	99	42.35
Vested	(55)	42.98
Forfeited	(5)	41.83
Unvested restricted stock awards at September 30, 2022	158	41.24
Granted	103	35.75
Vested	(69)	40.96
Forfeited	(19)	39.31
Unvested restricted stock awards at September 30, 2023	173	38.30
Granted	107	33.84
Vested	(80)	38.80
Forfeited	(5)	36.77
Unvested restricted stock awards at September 30, 2024	195	\$ 35.68

Restricted Stock Units and Deferred Stock Units

The Company has entered into restricted stock unit agreements with certain key employees in foreign jurisdictions and members of the Board, covering the issuance of common stock (“RSUs”). With respect to employees, RSUs generally vest at a 33% rate on each of the first three anniversaries following the grant date, and RSUs are settled in shares and issued to the employees if they are employed by the Company at the end of the vesting period. With respect to members of the Board, RSUs vest on a monthly pro-rata basis within the one-year period following the date of grant, and RSUs are settled in shares and generally issued upon termination of service as a Board member. RSUs are valued based on the market value of the shares as of the date of grant with the value allocated to expense evenly over the vesting period. The Company awarded approximately 14,000, 16,000 and 14,000 RSUs in fiscal 2024, 2023 and 2022, respectively. As of September 30, 2024 and 2023, outstanding RSUs (including unvested units and vested units not yet settled) totaled approximately 69,000 and 74,000 units, respectively, with a weighted average grant date fair value per unit of \$31.86 and \$32.18, respectively. The stock-based compensation table above includes RSU expenses recognized related to these awards, which totaled \$0.5 million in each of fiscal 2024, 2023 and 2022.

Directors may elect to receive their annual fees for services to the Board in deferred stock units (“DSUs”). DSUs are fully vested and expensed upon grant at the market value of the shares on the grant date. DSUs are settled in shares and issued to the Director upon termination of service as a Board member. As of September 30, 2024 and 2023, outstanding, fully vested DSUs totaled approximately 24,000 and 38,000 units, respectively, with a weighted average grant date fair value per unit of \$28.53 and \$30.86, respectively. The stock-based compensation expense table above includes DSU expenses recognized related to these awards, which totaled \$0.0 million, \$0.1 million and \$0.1 million in fiscal 2024, 2023 and 2022, respectively.

1999 Employee Stock Purchase Plan

Under the amended 1999 Employee Stock Purchase Plan (“ESPP”), the Company is authorized to issue up to 600,000 shares of common stock. All full-time and part-time U.S. employees can elect to have up to 10% of their annual compensation withheld, with an annual limit of \$25,000, to purchase the Company’s common stock at purchase prices defined within the provisions of the ESPP. ESPP share awards are valued based on the value of the discount feature plus the fair value of the optional features as of the date of grant using the Black-Scholes valuation model. The value of these share awards is allocated to expense evenly over each six-month purchase period. Employee contributions to the ESPP included in accrued compensation on the consolidated balance sheets totaled \$0.0 million and \$0.1 million as of September 30, 2024 and 2023, respectively. The stock-based compensation expense table above includes expenses recognized related to the ESPP, which totaled \$0.3 million in each of fiscal 2024, 2023 and 2022.

9. Income Taxes

Income taxes on the consolidated statements of operations consisted of the following:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Current expense (benefit):			
U.S. Federal	\$ 3,478	\$ 3,363	\$ (510)
U.S. State	663	591	(143)
International	215	250	166
Total current expense (benefit)	4,356	4,204	(487)
Deferred (benefit) expense:			
U.S. Federal	—	—	5,200
U.S. State	—	—	515
International	(320)	(181)	(447)
Total deferred (benefit) expense	(320)	(181)	5,268
Total income tax expense	\$ 4,036	\$ 4,023	\$ 4,781

The difference between amounts calculated at the statutory U.S. federal income tax rate of 21% and the Company's effective tax rate was as follows:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Amount at statutory U.S. federal income tax rate	\$ (1,576)	\$ 522	\$ (4,724)
Change because of the following items:			
State income taxes, net of federal benefit	(449)	(632)	(897)
Foreign and state rate differential	257	495	628
U.S. federal and foreign R&D credits	(732)	(1,544)	(1,511)
Valuation allowance change (1)	4,983	4,083	10,978
Stock-based compensation (2)	900	1,003	481
U.S. Federal and state rate change	169	(152)	—
Tax reserve change	(130)	734	(123)
Foreign-derived income deduction	(347)	(403)	—
Contingent consideration	9	(164)	13
Merger-related transaction costs	734	—	—
Other	218	81	(64)
Income tax expense	<u>\$ 4,036</u>	<u>\$ 4,023</u>	<u>\$ 4,781</u>

(1) In fiscal 2024 and 2023, the valuation allowance increased primarily as a result of the incremental deferred tax assets recorded during each respective period related to capitalized U.S. R&D expenses and Ireland net operating losses ("NOLs"). In fiscal 2022, the valuation allowance increased primarily as a result of the establishment of a full valuation allowance against U.S. net deferred tax assets as of September 30, 2022.

(2) Includes non-deductible stock-based compensation.

Excess tax benefits related to stock-based compensation expense are recorded within income tax expense on the consolidated statements of operations and totaled \$0.3 million, less than \$0.1 million and \$0.2 million for fiscal 2024, 2023 and 2022, respectively.

The components of deferred income taxes, net, consisted of the following and resulted from differences in the recognition of transactions for income tax and financial reporting purposes:

<i>(In thousands)</i>	September 30,	
	2024	2023
Depreciable assets	\$ (3,327)	\$ (3,802)
Deferred revenue	366	1,082
Accruals and reserves	2,305	2,052
Stock-based compensation	2,850	2,665
Impaired strategic investments	1,809	1,829
NOL carryforwards (1)	4,774	4,578
U.S. Federal and state R&D credits (2)	3,277	2,973
Capitalized R&D expenses	12,757	7,976
Other	604	648
Valuation allowance	(27,200)	(22,005)
Deferred taxes, net	<u>\$ (1,785)</u>	<u>\$ (2,004)</u>

(1) As of September 30, 2024, NOL carryforwards consisted of U.S. state NOL carryforwards of \$0.4 million and Ireland NOL carryforwards of \$4.4 million. U.S. state NOL carryforwards begin to expire in fiscal 2029. Ireland NOL carryforwards have an unlimited carryforward period.

(2) As of September 30, 2024, U.S. federal and state R&D credits begin to expire in fiscal 2029.

As of September 30, 2024 and 2023, valuation allowances against deferred tax assets, net, totaled \$27.2 million and \$22.0 million, respectively. Deferred tax assets represent amounts available to reduce income taxes payable on taxable income in future years. Such assets arise from NOLs and tax credits and are primarily a result of temporary differences between the financial reporting and tax bases of assets and liabilities. We evaluate the recoverability of deferred tax assets by assessing all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance for deferred tax assets is needed. A valuation allowance is established if it is more likely than not (defined as a likelihood of more than 50%) that all or a portion of deferred tax assets will not be realized. The determination of whether a valuation allowance should be established, as well as the amount of such allowance, requires significant judgment and estimates, including estimates of future earnings.

In evaluating the realizability of our net deferred tax assets, we perform an assessment each reporting period of both positive and negative evidence.

- As of September 30, 2024, we identified negative evidence that included the existence of three-year cumulative U.S. pre-tax losses adjusted for permanent adjustments and short-term future losses. Additionally, we identified positive evidence that included (i) our forecast of long-term future earnings, and (ii) future reversal of taxable temporary differences and carryforwards, though these did not provide sufficient evidence to support realization of the deferred tax assets.
- As of September 30, 2023, we identified negative evidence that included the existence of forecasted, short-term future losses. Additionally, we identified positive evidence that included (i) the existence of three-year cumulative U.S. pre-tax income adjusted for permanent adjustments, though this was primarily driven by revenue recognized on the final milestone payment received under the Abbott Agreement; (ii) our forecast of long-term future earnings; and (iii) future reversal of taxable temporary differences and carryforwards, though these did not provide sufficient evidence to support realization of the deferred tax assets.

We apply judgment to consider the relative impact of negative and positive evidence, and the weight given to negative and positive evidence is commensurate with the extent to which such evidence can be objectively verified. Objective historical evidence, such as cumulative three-year pre-tax losses adjusted for permanent adjustments, is given greater weight than subjective positive evidence, such as forecasts of future earnings. The more objective negative evidence that exists limits our ability to consider other, potentially positive, subjective evidence, such as our future earnings projections. Based on our evaluation of all available positive and negative evidence, and by placing greater weight on the objectively verifiable evidence, we determined, as of September 30, 2024, 2023 and 2022, that it is more likely than not that our net U.S. deferred tax assets will not be realized. In fiscal 2022, we recorded a full valuation allowance against our net U.S. deferred tax assets as of September 30, 2022, resulting in a non-cash charge to income tax expense of \$10.2 million in the fourth quarter of fiscal 2022. In fiscal 2024 and 2023, we maintained the full valuation allowance against our net U.S. deferred tax assets. 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.

Unrecognized tax benefits are the differences between a tax position taken, or expected to be taken in a tax return, and the benefit recognized for accounting purposes pursuant to accounting guidance. The following is a reconciliation of the changes in unrecognized tax benefits, excluding interest and penalties:

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Unrecognized tax benefits, beginning balance	\$ 3,443	\$ 2,793	\$ 2,887
Increases in tax positions for prior years	13	—	53
Decreases in tax positions for prior years	(28)	(4)	(35)
Increases in tax positions for current year	587	836	519
Lapse of the statute of limitations	(802)	(182)	(631)
Unrecognized tax benefits, ending balance	<u>\$ 3,213</u>	<u>\$ 3,443</u>	<u>\$ 2,793</u>

The total amount of unrecognized tax benefits excluding interest and penalties that, if recognized, would affect the effective tax rate was \$2.8 million and \$3.1 million as of September 30, 2024 and 2023, respectively. As of September 30, 2024, the Company does not expect the liability for unrecognized tax benefits to change significantly in the next 12 months and has classified the above balances on the consolidated balance sheets in other noncurrent liabilities. Interest and penalties related to unrecognized tax benefits are recorded in income tax expense on the consolidated statements of operations. The gross amount accrued for interest and penalties on unrecognized tax benefits was \$0.5 million as of each of September 30, 2024 and 2023.

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 during fiscal 2022; the examination has been completed. U.S. federal income tax returns for years prior to fiscal 2021 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 2014. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2020. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical, NorMedix and Vetex for periods prior to the respective acquisition dates, pursuant to the terms of the related share purchase agreements. As of September 30, 2024 and 2023, there were no undistributed earnings in foreign subsidiaries.

10. Defined Contribution Plans

The Company has a 401(k) retirement and savings plan for the benefit of qualifying U.S. employees, as well as a defined contribution Personal Retirement Savings Account plan for the benefit of qualifying Ireland employees. For eligible U.S. employees, effective January 1, 2022, the Company makes matching contributions of up to 4% of eligible compensation; prior to January 1, 2022, the Company made matching contributions of up to 3% of eligible compensation on employee contributions of up to 6% of eligible compensation. For eligible Ireland employees, the Company makes contributions of up to 8% of eligible compensation on employee contributions of up to 6% of eligible compensation. Expense recognized for Company contributions to defined contribution plans totaled \$1.9 million, \$1.9 million and \$1.7 million in fiscal 2024, 2023 and 2022, respectively.

11. Commitments and Contingencies

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 paid the sellers \$1.8 million in fiscal 2024. The Company is obligated to pay an additional installment of \$1.8 million in fiscal 2027. 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.

Asset Acquisition. 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, \$1.0 million in fiscal 2023, and \$0.9 million in fiscal 2024. An additional \$1.0 million payment is contingent upon the achievement of a certain regulatory milestone within a contingency period ending in 2033.

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, in fiscal 2023, we recorded \$1.3 million in severance and related charges in restructuring expense on our consolidated statements of operations. All associated expenses were paid as of September 30, 2023.

13. Merger Agreement

On May 28, 2024, Surmodics entered into the Merger Agreement with Parent and Merger Sub (Note 1). Pursuant to the Merger Agreement, and subject to the terms and conditions thereof, Merger Sub will merge (the "Merger") with and into the Company, with the Company as the surviving corporation and a wholly owned subsidiary of Parent. At the effective time of the Merger (the "Effective Time"), each share of common stock of the Company then outstanding (other than (1) those shares owned by Merger Sub, Parent, the Company, or any direct or indirect wholly owned subsidiary of Parent or the Company (which will be cancelled without any consideration), (2) any shares outstanding immediately prior to the Effective Time and held of record or beneficially by a Person who has not voted in favor of approval of this Agreement and who is entitled to demand and properly demands and perfects such holder's dissenter's rights with respect to such shares, and (3) any shares that have been issued as a restricted stock award pursuant to any of the Stock Incentive Plans (as defined in the Merger Agreement) and that remains unvested and subject to forfeiture thereunder ("Restricted Shares") (which will be treated as described below)) will be converted into the right to receive \$43.00 in cash, without interest (the "Merger Consideration"). The Merger is not subject to a financing condition. If the Merger is consummated, shares of our common stock will be delisted from The Nasdaq Stock Market and deregistered under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

During fiscal 2024, we incurred a total of \$3.7 million in Merger-related charges, which we reported within selling, general and administrative expenses on the consolidated statements of operations.

Merger Consideration

The Merger Agreement provides that, at the Effective Time, each of the Company's then outstanding equity awards will be treated as follows: (1) each restricted stock unit or deferred stock unit that has been issued pursuant to any of the Stock Incentive Plans will be cancelled in exchange for an amount in cash equal to the Merger Consideration net of any taxes withheld pursuant to the Merger Agreement; (2) each Restricted Share will be cancelled in exchange for an amount in cash equal to the Merger Consideration, net of any taxes withheld pursuant to the Merger Agreement; and (3) each unexercised option to acquire Company common stock will be (i) if the Merger Consideration for such option is equal to or greater than the exercise price per share of Company common stock subject to such option, cancelled in exchange for an amount in cash equal to the excess, if any, of the Merger Consideration over the exercise price per share of Company common stock subject to such option multiplied by the number of shares of Company common stock subject to such option, and (ii) if the Merger Consideration for such option is less than the exercise price per share of Company common stock subject to such option, cancelled for no consideration.

Conditions

The obligations of the parties to consummate the Merger are subject to the satisfaction or waiver of closing conditions set forth in the Merger Agreement, including (1) the approval of the Company's shareholders, (2) the expiration or termination of any waiting period applicable under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), (3) the absence of a "Company Material Adverse Effect" (as defined in the Merger Agreement) with respect to the Company and (4) other customary closing conditions.

The Merger was approved by Surmodics' shareholders at a special meeting on August 13, 2024. On the same date, the Company announced that it and an affiliate of Parent each received a request for additional information and documentary materials (a "Second Request") from the U.S. Federal Trade Commission ("FTC") in connection with the Merger. As of September 30, 2024, the Merger remained subject to the expiration or termination of the waiting period under the HSR Act, as well as other customary closing conditions.

Termination Rights & Fees

The Merger Agreement may be terminated with the mutual written consent of Parent and the Company and also contains termination rights for each of Parent and the Company, including, among others, (1) if the Merger has not been consummated by February 28, 2025 (which date may be extended one or more times, for up to nine additional months in total, under specified circumstances), (2) if a final and non-appealable judgment or law makes consummation of the Merger illegal or prevents the consummation of the Merger, (3) if the required approval of the Company's shareholders is not obtained, or (4) in the case of a material uncured breach by the other party, in each case as further described in, and subject to the terms and conditions of, the Merger Agreement. Parent may terminate the Merger Agreement in certain circumstances generally related to an adverse change in the Company's board of directors' recommendation in favor of the Merger and, as further described below, the Company may terminate the Merger Agreement to accept a Superior Proposal, as further described in, and subject to the terms and conditions of, the Merger Agreement.

Upon termination of the Merger Agreement under specified circumstances, generally relating to alternative acquisition proposals or an adverse change in the Company's board of directors' recommendation in favor of the Merger, the Company would be required to pay Parent a termination fee of \$20.4 million. Upon termination of the Merger Agreement under specified circumstances, generally relating to a failure of the Merger to be completed due to certain regulatory impediments, Parent would be required to pay the Company a reverse termination fee of \$50.2 million. In certain other circumstances, generally related to a failure by Parent to consummate the Merger when required to do so pursuant to the terms of the Merger Agreement, Parent would be required to pay the Company a reverse termination fee of \$47.0 million. The Merger Agreement also contains restrictions on the Company's ability to seek specific performance of Parent's obligation to consummate the Merger and generally limits the aggregate liability of Parent for a breach of the Merger Agreement to the amount of the termination fee payable by Parent to the Company.

The foregoing description of the Merger and the Merger Agreement does not purport to be and is not complete and is subject to and qualified in its entirety by reference to the full text of the Merger Agreement, a copy of which is included as Exhibit 2.5 to this Annual Report on Form 10-K.

14. Reportable Segment Information

Reportable segments are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, who is the Company's Chief Executive Officer, in deciding how to allocate resources and in assessing performance. We operate two reportable segments:

- **Medical Device:** Manufacture of performance coatings, including surface modification coating technologies to improve access, deliverability and predictable deployment of medical devices and drug-delivery coating technologies to provide site-specific drug-delivery from the surface of a medical device, with end markets that include neurovascular, peripheral, coronary, and structural heart, among others; and the manufacture of vascular intervention medical devices, including drug-coated balloons, mechanical thrombectomy devices, and radial access balloon catheters and guide sheaths.
- **In Vitro Diagnostics:** Manufacture of chemical and biological components used in in vitro diagnostic immunoassay and molecular tests within the diagnostic and biomedical research markets. Component products include protein stabilizers, surface coatings, substrates and antigens.

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

<i>(In thousands)</i>	Fiscal Year		
	2024	2023	2022
Revenue:			
Medical Device	\$ 97,508	\$ 105,783	\$ 72,389
In Vitro Diagnostics	28,570	26,801	27,562
Total revenue	<u>\$ 126,078</u>	<u>\$ 132,584</u>	<u>\$ 99,951</u>
Operating (loss) income:			
Medical Device	\$ (2,239)	\$ 5,084	\$ (22,923)
In Vitro Diagnostics	13,101	12,637	13,073
Total segment operating income (loss)	10,862	17,721	(9,850)
Corporate	(16,507)	(12,571)	(12,247)
Total operating (loss) income	<u>\$ (5,645)</u>	<u>\$ 5,150</u>	<u>\$ (22,097)</u>
Depreciation and amortization:			
Medical Device	\$ 7,901	\$ 7,874	\$ 8,368
In Vitro Diagnostics	377	321	355
Corporate	416	327	419
Total depreciation and amortization	<u>\$ 8,694</u>	<u>\$ 8,522</u>	<u>\$ 9,142</u>

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 litigation and merger-and-acquisition-related costs, 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.

Long-lived assets by country, including property and equipment and intangible assets net of accumulated depreciation and amortization, respectively, were as follows:

<i>(In thousands)</i>	September 30,	
	2024	2023
U.S.	\$ 22,348	\$ 23,525
Ireland	26,177	28,707

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

1. 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”) that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

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 September 30, 2024, the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, the Certifying Officers concluded that the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective as of September 30, 2024, as designed and implemented 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.

2. Internal Control over Financial Reporting

a. Management’s Annual Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). The Company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our consolidated financial statements.

Management evaluated the design and operating effectiveness of the Company’s internal control over financial reporting based on the criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation, management concluded that internal control over financial reporting was effective as of September 30, 2024.

The Company’s independent registered public accounting firm, Deloitte & Touche LLP, who audited the consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on the effectiveness of the Company’s internal control over financial reporting as of September 30, 2024. This report states that internal control over financial reporting was effective and appears in “Financial Statements and Supplementary Data” in Part II, Item 8 of this Annual Report on Form 10-K.

b. Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended September 30, 2024 that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

During the three months ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not Applicable.

PART III**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The information required by Item 10 relating to directors, our audit committee, the nature of changes, if any, to procedures by which our shareholders may recommend nominees for directors, our code of ethics, our insider trading policy and compliance with Section 16(a) of the Exchange Act may be incorporated by reference from the Company's Proxy Statement for its 2025 Annual Meeting of Shareholders, or alternatively, disclosed in an amendment to this Annual Report on Form 10-K. The information required by Item 10 relating to executive officers appears in Part I, Item 1 of this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by Item 11 may be incorporated by reference from the Company's Proxy Statement for its 2025 Annual Meeting of Shareholders, or alternatively, disclosed in an amendment to this Annual Report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by Item 12 may be incorporated by reference from the Company's Proxy Statement for its 2025 Annual Meeting of Shareholders, or alternatively, disclosed in an amendment to this Annual Report on Form 10-K.

Equity Compensation Plan Information

The following table provides information related to the Company's equity compensation plans in effect as of September 30, 2024:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by shareholders	1,516,759 (1) \$	37.12 (1)	528,732
Equity compensation plans not approved by shareholders	—	N/A	—
Total	1,516,759 \$	37.12	528,732

(1) Excludes shares that may be issued under the Company's amended and restated 1999 Employee Stock Purchase Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by Item 13 may be incorporated by reference from the Company's Proxy Statement for its 2025 Annual Meeting of Shareholders, or alternatively, disclosed in an amendment to this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by Item 14 may be incorporated by reference from the Company's Proxy Statement for its 2025 Annual Meeting of Shareholders, or alternatively, disclosed in an amendment to this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) 1. Financial Statements

The following consolidated financial statements are set forth in Part II, Item 8:

[Reports of Independent Registered Public Accounting Firm](#)

[Consolidated Balance Sheets](#)

[Consolidated Statements of Operations](#)

[Consolidated Statements of Comprehensive \(Loss\) Income](#)

[Consolidated Statements of Stockholders' Equity](#)

[Consolidated Statements of Cash Flows](#)

[Notes to Consolidated Financial Statements](#)

2. Financial Statement Schedules

Schedule II —Valuation and Qualifying Accounts for fiscal years ended September 30, 2024, 2023 and 2022. All other schedules are omitted because they are inapplicable, not required, or the information is in the consolidated financial statements or related notes.

Surmodics, Inc. Schedule II – Valuation and Qualifying Accounts

<i>(In thousands)</i>	Balance at Beginning of Fiscal Year	Additions: Charges to Income	Deductions: Other Changes (Debit) Credit	Balance at End of Fiscal Year
Allowance for credit losses:				
Fiscal year ended September 30, 2022	\$ 119	5	(43) (a)	\$ 81
Fiscal year ended September 30, 2023	81	37	(38) (a)	80
Fiscal year ended September 30, 2024	80	64	— (a)	144

(a) Primarily consists of uncollectible accounts written off, less recoveries.

3. Exhibits

<u>Exhibit</u>	<u>Description</u>
<u>2.1</u>	<u>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 filed on November 27, 2015.</u>
<u>2.2</u>	<u>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 Current Report on Form 8-K filed on January 13, 2016.</u>
<u>2.3</u>	<u>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.</u>
<u>2.4</u>	<u>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.</u>
<u>2.5</u>	<u>Merger Agreement, dated as of May 28, 2024, by and among Surmodics, Inc., BCE Parent, LLC and BCE Merger Sub, Inc. — incorporated by reference to Exhibit 2.1 to the Company’s Current Report on Form 8-K dated May 28, 2024.</u>
<u>3.1</u>	<u>Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 to the Company’s Quarterly Report on Form 10-Q filed on July 29, 2016</u>
<u>3.2</u>	<u>Restated Bylaws of Surmodics, Inc., as amended August 27, 2024 — incorporated by reference to Exhibit 3.2 to the Company’s Quarterly Report on Form 10-Q filed on July 31, 2024.</u>
<u>4.1</u>	<u>Description of Securities of Surmodics, Inc. — incorporated by reference to Exhibit 4.1 to the Company’s Annual Report on Form 10-K filed on December 3, 2019.</u>
<u>10.1*</u>	<u>Form of Incentive Stock Option Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed on February 12, 2010.</u>
<u>10.2*</u>	<u>Form of Non-Statutory Stock Option Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company’s Current Report on Form 8-K filed on February 12, 2010.</u>
<u>10.3*</u>	<u>Surmodics, Inc. 2009 Equity Incentive Plan (as amended and restated on February 17, 2016) — incorporated by reference to Appendix B to the Company’s Definitive Proxy Statement for the annual meeting of shareholders held on February 17, 2016 filed on January 8, 2016.</u>
<u>10.4*</u>	<u>Surmodics, Inc. 1999 Employee Stock Purchase Plan (as amended and restated on February 17, 2016) — incorporated by reference to Appendix D to the Company’s Definitive Proxy Statement for the annual meeting of shareholders held on February 17, 2016 filed on January 8, 2016.</u>
<u>10.5*</u>	<u>Severance Agreement by and between Gary R. Maharaj and Surmodics, Inc. dated as of December 14, 2010 — incorporated by reference to Exhibit 10.2 to the Company’s Quarterly Report on Form 10-Q filed on February 4, 2011.</u>
<u>10.6*</u>	<u>Change of Control Agreement with Charles W. Olson dated February 9, 2012 — incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed on February 10, 2012.</u>
<u>10.7*</u>	<u>Amendment dated February 9, 2015 to Change of Control Agreement with Charles W. Olson dated February 9, 2012 — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on February 13, 2015.</u>
<u>10.8*</u>	<u>Change of Control Agreement with Joseph J. Stich dated February 9, 2012 — incorporated by reference to Exhibit 10.4 to the Company’s Current Report on Form 8 K filed on February 10, 2012.</u>
<u>10.9*</u>	<u>Amendment dated February 9, 2015 to Change of Control Agreement with Joseph J. Stich dated February 9, 2012 — incorporated by reference to Exhibit 10.4 to the Company’s Current Report on Form 8-K filed on February 13, 2015.</u>
<u>10.10*</u>	<u>Form of Change of Control Agreement with Executive Officers — incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed on February 7, 2020.</u>

Exhibit	Description
<u>10.11*</u>	<u>Form of Restricted Stock Unit Award Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.2 to the Company’s Quarterly Report on Form 10-Q filed on May 8, 2014.</u>
<u>10.12*</u>	<u>Form of Restricted Stock Unit Award Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company’s Quarterly Report on Form 10-Q filed on February 4, 2015.</u>
<u>10.13*</u>	<u>Form of Deferred Stock Unit Master Agreement (Quarterly Awards) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company’s Quarterly Report on Form 10-Q filed on February 8, 2013.</u>
<u>10.14*</u>	<u>Form of Deferred Stock Unit Master Agreement (Quarterly Awards) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company’s Quarterly Report on Form 10-Q filed on February 4, 2015.</u>
<u>10.15*</u>	<u>Form of Restricted Stock Unit Award Agreement (Employee) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on February 22, 2016.</u>
<u>10.16*</u>	<u>Omnibus Amendment to Certain Equity Agreements with Non-Employee Directors under the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed on May 8, 2014.</u>
<u>10.17*</u>	<u>Form of Non-Statutory Stock Option Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company’s Quarterly Report on Form 10-Q filed on May 8, 2014.</u>
<u>10.18**</u>	<u>Development and Distribution Agreement between Surmodics, Inc. and Abbott Vascular, Inc., dated as of February 26, 2018. — incorporated by reference to Exhibit 10.2 to the Company’s Quarterly Report on Form 10-Q filed on May 4, 2018.</u>
<u>10.19*</u>	<u>Change of Control Agreement by and between Surmodics, Inc. and Teri W. Sides, dated as of October 30, 2018 — incorporated by reference to Exhibit 10.34 to the Company’s Annual Report on Form 10-K filed on November 30, 2018.</u>
<u>10.20*</u>	<u>Surmodics, Inc. 2019 Equity Incentive Plan, as amended and restated February 9, 2023 — incorporated by reference to Appendix B to the Company’s Schedule 14A filed on December 19, 2022.</u>
<u>10.21*</u>	<u>Form of Non-Qualified Stock Option Award Agreement for the Surmodics, Inc. 2019 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on May 6, 2019.</u>
<u>10.22*</u>	<u>Form of Restricted Stock Award Agreement for the Surmodics, Inc. 2019 Equity Incentive Plan — incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed on May 6, 2019.</u>
<u>10.23*</u>	<u>Form of Restricted Stock Unit Award Agreement (Employee) for the Surmodics, Inc. 2019 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company’s Current Report on Form 8-K filed on May 6, 2019.</u>
<u>10.24*</u>	<u>Form of Restricted Stock Unit Award Agreement (Director) for the Surmodics, Inc. 2019 Equity Incentive Plan — incorporated by reference to Exhibit 10.5 to the Company’s Current Report on Form 8-K filed on May 6, 2019.</u>
<u>10.25*</u>	<u>Form of Deferred Stock Unit Master Agreement (for non-employee directors) for the Surmodics, Inc. 2019 Equity Incentive Plan — incorporated by reference to Exhibit 10.6 to the Company’s Current Report on Form 8-K filed on May 6, 2019.</u>
<u>10.26*</u>	<u>Surmodics, Inc. Board Compensation Policy, Amended and restated as of September 23, 2021 — incorporated by reference to Exhibit 10.27 to the Company’s Annual Report on Form 10-K filed on November 24, 2021.</u>
<u>10.27</u>	<u>Loan and Security Agreement dated as of September 14, 2020 among Surmodics, Inc. et al. and Bridgewater Bank — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on September 15, 2020.</u>
<u>10.28</u>	<u>First Amendment to Loan and Security Agreement dated as of July 2, 2021 by and among Surmodics, Inc., the other loan parties party thereto, and Bridgewater Bank — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K dated July 2, 2021.</u>
<u>10.29</u>	<u>Second Amendment to Loan and Security Agreement dated as of March 7, 2022 by and among Surmodics, Inc., the other loan parties party thereto, and Bridgewater Bank — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on March 7, 2022.</u>

Exhibit	Description
<u>10.30*</u>	<u>Form of Restricted Stock Unit Award Agreement (Non-Employee Director) for the Surmodics, Inc. 2019 Equity Incentive Plan — incorporated by reference to Exhibit 10.32 to the Company’s Annual Report on Form 10-K filed on December 2, 2020.</u>
<u>10.31</u>	<u>Lease Agreement by and among Surmodics, Inc., MN Golden 1, LLC and MN Golden 2, LLC, as amended February 24, 2023 – incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed on April 26, 2023.</u>
<u>10.32</u>	<u>Credit, Security and Guaranty Agreement dated as of October 14, 2022 by and among Surmodics, Inc., Surmodics Shared Services, LLC, Surmodics Holdings, LLC, Surmodics Coatings, LLC, SurModics MD, LLC, Surmodics Coatings Mfg, LLC, Surmodics IVD, Inc., NorMedix, Inc., and Surmodics MD Operations, LLC, as borrowers, the guarantors from time to time party thereto, MidCap Funding IV Trust and MidCap Financial Trust and the lenders from time to time party thereto (excluding schedules and exhibits, which Surmodics, Inc. agrees to furnish to the Securities and Exchange Commission upon request) — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on October 17, 2022.</u>
<u>10.33*</u>	<u>Executive Transaction Bonus Program — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K dated May 28, 2024.</u>
<u>10.34*</u>	<u>Form of Bonus Agreement — incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K dated May 28, 2024.</u>
<u>19.1†</u>	<u>Surmodics, Inc. Securities Trading Policy.</u>
<u>21†</u>	<u>Subsidiaries of the Registrant.</u>
<u>23†</u>	<u>Consent of Deloitte & Touche LLP.</u>
<u>24</u>	<u>Power of Attorney (included on signature page of this Form 10-K).</u>
<u>31.1†</u>	<u>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.</u>
<u>31.2†</u>	<u>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.</u>
<u>32.1†</u>	<u>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.</u>
<u>32.2†</u>	<u>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.</u>
<u>97</u>	<u>Surmodics, Inc. Policy on Recovery of Erroneously Awarded Compensation — incorporated by reference to Exhibit 97.1 to the Company’s Annual Report on Form 10-K filed on November 22, 2023.</u>
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).

* Management contract or compensatory plan or arrangement.

† Filed herewith.

** Portions of this document, which have been separately filed with the Securities and Exchange Commission, have been omitted pursuant to a request for confidential treatment.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

SURMODICS, INC.

By: /s/ Gary R. Maharaj
Gary R. Maharaj
President and Chief Executive Officer

Dated: November 20, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant, in the capacities, and on the dates indicated.

(Power of Attorney)

Each person whose signature appears below authorizes GARY R. MAHARAJ or TIMOTHY J. ARENS, and constitutes and appoints said persons as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, authorizing said persons and granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gary R. Maharaj</u> Gary R. Maharaj	President and Chief Executive Officer (principal executive officer) and Director	November 20, 2024
<u>/s/ Timothy J. Arens</u> Timothy J. Arens	Senior Vice President of Finance and Chief Financial Officer (principal financial officer)	November 20, 2024
<u>/s/ John D. Manders</u> John D. Manders	Vice President of Finance and Corporate Controller (principal accounting officer)	November 20, 2024
<u>/s/ Susan E. Knight</u> Susan E. Knight	Chairman of the Board of Directors	November 20, 2024
<u>/s/ José H. Bedoya</u> José H. Bedoya	Director	November 20, 2024
<u>/s/ David R. Dantzker, M.D.</u> David R. Dantzker, M.D.	Director	November 20, 2024
<u>/s/ Lisa Wipperman Heine</u> Lisa Wipperman Heine	Director	November 20, 2024

Surmodics, Inc.

Annual Report on

Form 10-K

for the fiscal year ended

September 30, 2024