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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2022**

**or**

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

**For the transition period from to**

**Commission file number: 001-36536**

# CAREDX, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **94-3316839** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**1 Tower Place**
**South San Francisco, California 94080**
**(Address of principal executive offices and zip code)**

**(415) 287-2300**
**(Registrant's telephone number, including area code)**

**N/A**
**(Former name, former address and former fiscal year, if changed since last report)**

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

| **Title of Each Class** | **Trading Symbol** | **Name of Each Exchange on Which Registered** |
|---|---|---|
| Common Stock, par value $0.001 per share | CDNA | The Nasdaq Stock Market LLC |

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

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

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

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

There were 53,221,125 shares of the registrant's Common Stock issued and outstanding as of May 3, 2022.

**CareDx, Inc.**
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**PART I. FINANCIAL INFORMATION**

**ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**CareDx, Inc.**
**Condensed Consolidated Balance Sheets**
**(Unaudited)**
**(In thousands, except share data)**

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 171,892 | $ 348,485 |
| Marketable securities | 147,330 | — |
| Accounts receivable | 65,320 | 59,761 |
| Inventory | 18,212 | 17,186 |
| Prepaid and other current assets | 8,733 | 7,928 |
| Total current assets | 411,487 | 433,360 |
| Property and equipment, net | 27,564 | 22,044 |
| Operating leases right-of-use assets | 17,122 | 17,993 |
| Intangible assets, net | 48,149 | 50,195 |
| Goodwill | 36,983 | 36,983 |
| Restricted cash | 214 | 211 |
| Other assets | 5,192 | 5,835 |
| Total assets | $ 546,711 | $ 566,621 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 10,605 | $ 13,337 |
| Accrued compensation | 11,418 | 26,042 |
| Accrued and other liabilities | 44,897 | 37,922 |
| Total current liabilities | 66,920 | 77,301 |
| Deferred tax liability | 194 | 415 |
| Common stock warrant liability | 112 | 139 |
| Deferred payments for intangible assets | 4,959 | 5,041 |
| Operating lease liability, less current portion | 16,729 | 17,394 |
| Other liabilities | 253 | 455 |
| Total liabilities | 89,167 | 100,745 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity: | | |
| Preferred stock: $0.001 par value; 10,000,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued and outstanding at March 31, 2022 and December 31, 2021 | — | — |
| Common stock: $0.001 par value; 100,000,000 shares authorized at March 31, 2022 and December 31, 2021; 53,085,273 shares and 52,923,360 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively | 52 | 52 |
| Additional paid-in capital | 865,419 | 853,683 |
| Accumulated other comprehensive loss | (5,090) | (4,670) |
| Accumulated deficit | (402,837) | (383,189) |
| Total stockholders' equity | 457,544 | 465,876 |
| Total liabilities and stockholders' equity | $ 546,711 | $ 566,621 |

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

**CareDx, Inc.**
**Condensed Consolidated Statements of Operations**
**(Unaudited)**
**(In thousands, except share and per share data)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Revenue: | | |
| Testing services revenue | $ 66,444 | $ 59,281 |
| Product revenue | 6,788 | 5,778 |
| Patient and digital solutions revenue | 6,184 | 2,341 |
| Total revenue | 79,416 | 67,400 |
| Operating expenses: | | |
| Cost of testing services | 17,628 | 16,483 |
| Cost of product | 4,399 | 3,647 |
| Cost of patient and digital solutions | 4,855 | 1,449 |
| Research and development | 21,880 | 16,004 |
| Sales and marketing | 23,148 | 15,452 |
| General and administrative | 26,559 | 15,223 |
| Total operating expenses | 98,469 | 68,258 |
| Loss from operations | (19,053) | (858) |
| Other income (expense): | | |
| Interest income, net | 189 | 126 |
| Change in estimated fair value of common stock warrant liability | 27 | 27 |
| Other expense, net | (823) | (245) |
| Total other expense | (607) | (92) |
| Loss before income taxes | (19,660) | (950) |
| Income tax benefit | 12 | 263 |
| Net loss | $ (19,648) | $ (687) |
| Net loss per share (Note 3): | | |
| Basic | $ (0.37) | $ (0.01) |
| Diluted | $ (0.37) | $ (0.01) |
| Weighted-average shares used to compute net loss per share: | | |
| Basic | 53,015,459 | 51,181,160 |
| Diluted | 53,015,459 | 51,181,160 |

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

**CareDx, Inc.**
**Condensed Consolidated Statements of Comprehensive Loss**
**(Unaudited)**
**(In thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Net loss | $ (19,648) | $ (687) |
| Other comprehensive loss: | | |
| Foreign currency translation adjustments, net of tax | (420) | (1,503) |
| Net comprehensive loss | $ (20,068) | $ (2,190) |

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

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

| | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance at December 31, 2021 | 52,923,360 | $ 52 | $ 853,683 | $ (4,670) | $ (383,189) | $ 465,876 |
| Issuance of common stock under ESPP | 25,852 | — | 999 | — | — | 999 |
| RSU settlements, net of shares withheld | 64,819 | — | (1,482) | — | — | (1,482) |
| Issuance of common stock for services | 1,249 | — | 58 | — | — | 58 |
| Issuance of common stock for cash upon exercise of stock options | 69,993 | — | 1,598 | — | — | 1,598 |
| Employee stock-based compensation expense | — | — | 10,563 | — | — | 10,563 |
| Foreign currency translation adjustment | — | — | — | (420) | — | (420) |
| Net loss | — | — | — | — | (19,648) | (19,648) |
| Balance at March 31, 2022 | 53,085,273 | $ 52 | $ 865,419 | $ (5,090) | $ (402,837) | $ 457,544 |

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

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

| | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance at December 31, 2020 | 49,441,166 | $ 49 | $ 632,253 | $ (2,096) | $ (352,527) | $ 277,679 |
| Issuance of common shares through public equity offering, net of commissions and offering costs of $12,495 | 2,211,538 | 2 | 188,753 | — | — | 188,755 |
| Issuance of common stock under ESPP | 24,052 | — | 838 | — | — | 838 |
| RSU settlements, net of shares withheld | 121,447 | — | (2,313) | — | — | (2,313) |
| Issuance of common stock for services | 1,339 | — | 96 | — | — | 96 |
| Issuance of common stock for cash upon exercise of stock options | 139,579 | — | 2,193 | — | — | 2,193 |
| Employee stock-based compensation expense | — | — | 6,488 | — | — | 6,488 |
| Foreign currency translation adjustment | — | — | — | (1,503) | — | (1,503) |
| Net loss | — | — | — | — | (687) | (687) |
| Balance at March 31, 2021 | 51,939,121 | $ 51 | $ 828,308 | $ (3,599) | $ (353,214) | $ 471,546 |

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

**CareDx, Inc.**
**Condensed Consolidated Statements of Cash Flows**
**(Unaudited)**
**(In thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Operating activities:** | | |
| Net loss | $ (19,648) | $ (687) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Stock-based compensation | 10,634 | 6,547 |
| Revaluation of common stock warrant liability to estimated fair value | (27) | (27) |
| Depreciation and amortization | 2,619 | 1,950 |
| Amortization of right-of-use assets | 915 | 677 |
| Unrealized loss on long-term marketable equity securities | 507 | — |
| Revaluation of contingent consideration to estimated fair value | 64 | (44) |
| Amortization of premium on short-term marketable securities, net | 139 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (5,591) | (8,755) |
| Inventory | (1,060) | (4,056) |
| Prepaid and other assets | (567) | (3,628) |
| Operating leases liabilities, net | (969) | (320) |
| Accounts payable | (1,549) | 1,496 |
| Accrued compensation | (14,634) | (7,662) |
| Accrued and other liabilities | 7,916 | 1,661 |
| Refund liability - CMS advance payment | — | (20,496) |
| Change in deferred taxes | (217) | (286) |
| Net cash used in operating activities | (21,468) | (33,630) |
| **Investing activities:** | | |
| Acquisition of business, net of cash acquired | — | (3,543) |
| Acquisition of intangible assets | (100) | (1,200) |
| Purchases of short-term marketable securities | (148,522) | — |
| Maturities of short-term marketable securities | 1,053 | 25,072 |
| Additions of capital expenditures, net | (8,463) | (1,250) |
| Net cash (used in) provided by investing activities | (156,032) | 19,079 |
| **Financing activities:** | | |
| Proceeds from issuance of common shares in public equity offering, net of issuance costs paid | — | 188,715 |
| Proceeds from issuance of common stock under employee stock purchase plan | 999 | 667 |
| Taxes paid related to net share settlement of restricted stock units | (1,482) | (2,313) |
| Proceeds from exercise of stock options | 1,598 | 2,193 |
| Principal payments on finance lease obligations | — | (34) |
| Payment of contingent consideration | (250) | — |
| Net cash provided by financing activities | 865 | 189,228 |
| Effect of exchange rate changes on cash and cash equivalents | 45 | (23) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (176,590) | 174,654 |
| Cash, cash equivalents, and restricted cash at beginning of period | 348,696 | 134,939 |
| Cash, cash equivalents, and restricted cash at end of period | $ 172,106 | $ 309,593 |

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

## 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc. (“CareDx” or the “Company”), together with its subsidiaries, is a leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. The Company’s headquarters are in South San Francisco, California. The primary operations are in Brisbane, California; Omaha, Nebraska; Fremantle, Australia; and Stockholm, Sweden.

The Company’s commercially available testing services consist of AlloSure® Kidney, a donor-derived cell-free DNA (“dd-cfDNA”) solution for kidney transplant patients, AlloMap® Heart, a gene expression solution for heart transplant patients, AlloSure® Heart, a dd-cfDNA solution for heart transplant patients, and AlloSure® Lung, a dd-cfDNA solution for lung transplant patients. The Company has initiated several clinical studies to generate data on its existing and planned future testing services. In April 2020, the Company announced its first biopharma research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy transplants. The Company also offers high-quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. In 2019, the Company began providing digital solutions to transplant centers following the acquisitions of Ottr Complete Transplant Management (“Ottr”) and XynManagement, Inc. (“XynManagement”), as well as the acquisitions of TransChart LLC (“TransChart”), MedActionPlan.com, LLC (“MedActionPlan”) and The Transplant Pharmacy (“TTP”) in 2021.

Testing Services

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017. The Medicare reimbursement rate for AlloSure Kidney is currently $2,841. AlloSure Kidney has received positive coverage decisions from several commercial payers, and is reimbursed by other private payers on a case-by-case basis.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently $3,240. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

In October 2020, AlloSure Heart received a final Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, the Company's Medicare Administrative Contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently $2,753.

In May 2021, the Company purchased a minority investment of common stock in the biotechnology company Miromatrix Medical, Inc. (“Miromatrix”), for $5.0 million, and the investment is marked to market. Miromatrix works to eliminate the need for an organ transplant waiting list through the development of implantable engineered biological organs.

Clinical Studies

In January 2018, the Company initiated the Kidney Allograft Outcomes AlloSure Kidney Registry study (“K-OAR”), to develop additional data on the clinical utility of AlloSure Kidney for surveillance of kidney transplant recipients. K-OAR is a multicenter, non-blinded, prospective observational cohort study which has enrolled more than 1,700 renal transplant patients who will receive AlloSure Kidney long-term surveillance.

In September 2018, the Company initiated the Surveillance HeartCare™ Outcomes Registry (“SHORE”). SHORE is a prospective, multi-center, observational registry of patients receiving HeartCare for surveillance. HeartCare combines the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure® Heart in one surveillance solution.

In February 2019, AlloSure® Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. In June 2020, the Company submitted an AlloSure Lung application to the Palmetto MolDx Technical Assessment program seeking coverage and reimbursement for Medicare beneficiaries.

In September 2019, the Company announced the commencement of the Outcomes of KidneyCare on Renal Allografts (“OKRA”) study, which is an extension of K-OAR. OKRA is a prospective, multi-center, observational, registry of patients receiving KidneyCare for surveillance. KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the predictive artificial intelligence technology of iBox for a multimodality surveillance solution. The Company has not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or KidneyCare.

Products

The Company’s suite of AlloSeq products are commercial next generation sequencing (“NGS”)-based kitted solutions. These products include: AlloSeq™ Tx, a high-resolution Human Leukocyte Antigen (“HLA”) typing solution, AlloSeq™ cfDNA, a surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq™ HCT, a solution for chimerism testing for stem cell transplant recipients.

The Company's other HLA typing products include: TruSight HLA, a NGS-based high resolution typing solution; Olerup SSP®, based on the sequence specific primer (“SSP”) technology; and QTYPE®, which uses real-time polymerase chain reaction (“PCR”) methodology, to perform HLA typing.

In March 2021, the Company acquired certain assets of BFS Molecular S.R.L. (“BFS Molecular”), a software company focused on NGS-based patient testing solutions. BFS Molecular brings extensive software and algorithm development capabilities for NGS transplant surveillance products.

Patient and Digital Solutions

Following the acquisitions of both Ottr and XynManagement, the Company is a leading provider of transplant patient management software (“Ottr software”), as well as of transplant quality tracking and waitlist management solutions. Ottr software provides comprehensive solutions for transplant patient management and enables integration with electronic medical record (“EMR”) systems providing patient surveillance management tools and outcomes data to transplant centers. XynManagement provides two unique solutions, XynQAPI software (“XynQAPI”) and XynCare. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients ("SRTR") reporting. XynCare includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

In September 2020, the Company launched AlloCare, a mobile app that provides a patient-centric resource for transplant recipients to manage medication adherence, coordinate with Patient Care Managers for AlloSure scheduling and measure health metrics.

In January 2021, the Company acquired TransChart. TransChart provides EMR software to hospitals throughout the U.S. to care for patients who have or may need an organ transplant. As part of the Company's acquisition of TransChart in January 2021, the Company acquired TxAccess, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs, closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

In June 2021, the Company acquired the Transplant Hero patient application. The application helps patients manage their medications through alarms and interactive logging of medication events.

Also in June 2021, the Company entered into a strategic agreement with OrganX to develop clinical decision support tools across the transplant patient journey. Together, the Company and OrganX will develop advanced analytics that integrate AlloSure, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system. The Company has agreed to potential future milestone payments.

In November 2021, the Company acquired MedActionPlan, a New Jersey-based provider of medication safety, medication adherence and patient education. MedActionPlan is a leader in patient medication management for transplant patients and beyond.

In December 2021, the Company acquired TTP, a transplant focused pharmacy located in Mississippi. TTP provides individualized transplant pharmacy services for patients at multiple transplant centers located throughout the U.S.

COVID-19 Pandemic

The full impact of the continued COVID-19 pandemic, including the impact associated with preventative and precautionary measures that the Company, other businesses and governments have taken and may take, continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company, but the pandemic may materially affect the Company's financial condition, liquidity and future results of operations.

In the final weeks of March and during April 2020, with hospitals increasingly caring for COVID-19 patients, hospital administrators chose to limit or even defer, non-emergency procedures. Immunosuppressed transplant patients either self-prescribed or were asked to avoid transplant centers and caregiver visits to reduce the risk of contracting COVID-19. As a result, with transplant surveillance visits down, the Company experienced a slowdown in testing services volumes in the final weeks of March and during April 2020. As a response to the COVID-19 pandemic, and to enable immune-compromised transplant patients to continue to have their blood drawn, in late March 2020, the Company launched RemoTraC, a remote

home-based blood draw solution using mobile phlebotomy for AlloSure and AlloMap surveillance tests, as well as for other standard monitoring tests.

To date, more than 200 transplant and nephrology centers can offer RemoTraC to their patients and over 12,000 kidney, heart and lung transplant patients have enrolled. Based on existing and new relationships with partners, the Company has established a nationwide network of approximately 10,000 mobile phlebotomists. Following the introduction of RemoTraC and with the easing of stay-at-home restrictions and the opening up of many hospitals to non-COVID-19 patients, the Company has been able to maintain low levels of interruption to its testing services volumes.

There continues to be uncertainty around the COVID-19 pandemic as the Omicron variant has caused an increase in COVID-19 cases globally, impacted the availability of medical personnel in transplant centers and the volume of transplant procedures. A sustained reduction in transplant volume can negatively impact the testing volumes, as the Company saw in early part of first quarter of 2022.

The Company's product business experienced a reduction in forecasted sales volume throughout the second and third quarters of 2020, as it was unable to undertake onsite discussions and demonstrations of its recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark authorization in May 2020. The Company's product business regained normalized sales volumes during the fourth quarter of 2020.

The Company is maintaining its testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among employees. In areas where COVID-19 impacts healthcare operations, the Company's field-based sales and clinical support teams are supporting providers through virtual platforms. Although the executive orders that placed certain restrictions on operations in San Mateo County and the State of California, where the Company's laboratory and headquarters are located, were lifted effective June 15, 2021, new orders or restrictions could be adopted in the future depending upon the COVID-19 transmission rates in the Company's county and state, as well as other factors.

In addition, the Company has created a COVID-19 task force that is responsible for crisis decision making, employee communications, and enforcing all safety, monitoring and testing protocols in line with local regulations.

Liquidity and Capital Resources

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $402.8 million at March 31, 2022. As of March 31, 2022, the Company had cash, cash equivalents and marketable securities of $319.2 million and no debt outstanding.

*CMS Accelerated and Advance Payment Program for Medicare Providers*

On March 27, 2020 the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”). Pursuant to the CARES Act, the Centers for Medicare & Medicaid Services (“CMS”) expanded its Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submitted a request to the appropriate Medicare Administrative Contractor and met the required qualifications. During April 2020, the Company received an advance payment from CMS of approximately $20.5 million, and recorded the payment as Deferred revenue - CMS advance payment on the Company's condensed consolidated balance sheet. During December 2020, the Company reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021.

*January 2021 Underwritten Public Offering of Common Stock*

On January 25, 2021, the Company sold 1,923,077 shares of its common stock through an underwritten public offering at a public offering price of $91.00 per share. The net proceeds to the Company from the offering were approximately $164.0 million, after deducting underwriting discounts and commissions and offering expenses.

On February 11, 2021, the Company sold 288,461 shares of its common stock pursuant to the full exercise of the overallotment option granted to the underwriters in connection with the offering. The net proceeds to the Company from the full exercise of the underwriters' overallotment option were approximately $24.7 million.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies and estimates used in preparation of the unaudited condensed consolidated financial statements are described in the Company’s audited consolidated financial statements as of and for the year ended December 31, 2021, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on February 24, 2022. Material changes

to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 are reflected below.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and follow the requirements of the SEC for interim reporting. As permitted under those rules, certain notes and other financial information that are normally required by U.S. GAAP can be condensed or omitted. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the Company's financial information. The condensed consolidated balance sheet as of December 31, 2021 has been derived from audited consolidated financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three months ended March 31, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the unaudited condensed consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to transaction price estimates used for testing services revenue; standalone fair value of patient and digital solutions revenue performance obligations; accrued expenses for clinical studies; inventory valuation; the fair value of assets and liabilities acquired in a business combination or an assets acquisition (including identifiable intangible assets acquired); the fair value of contingent consideration recorded in connection with a business combination or an asset acquisition; the grant date fair value assumptions used to estimate stock-based compensation expense; income taxes; impairment of long-lived assets and indefinite-lived assets (including goodwill); and legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

For the three months ended March 31, 2022 and 2021, approximately 54% and 60%, respectively, of total revenue was derived from Medicare.

As of March 31, 2022 and December 31, 2021, approximately 28% and 27%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable at either March 31, 2022 or December 31, 2021.

Marketable Securities

The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities. As of March 31, 2022, the Company's short-term marketable securities consisted of corporate debt securities with maturities of greater than three months but less than twelve months at the time of purchase, which were classified as current assets on the condensed consolidated balance sheet.

The Company classifies its short-term marketable securities as held-to-maturity at the time of purchase and reevaluates such designation at each balance sheet date. The Company has the positive intent and ability to hold these marketable securities to maturity. Short-term marketable securities are carried at amortized cost and are adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income (expense), net on the condensed consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on short-term marketable securities are included in interest income (expense), net. The cost of securities sold will be determined using specific identification.

The Company considers investments in securities with remaining maturities of over one year as long-term investments. As of March 31, 2022, the Company's long-term marketable securities consisted of corporate equity securities and corporate debt securities. These long-term marketable securities are classified as other assets on the condensed consolidated balance sheet.

The Company classifies its long-term marketable debt securities as available-for-sale and reevaluates such designation at each balance sheet date. Unrealized gains and losses from the reevaluation of the long-term marketable debt securities, if any, are included in other comprehensive gain (loss) in the condensed consolidated statement of comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary, if any, on long-term marketable securities are included in interest income, net.

The Company records its long-term marketable equity securities at fair market value. Unrealized gains and losses from the remeasurement of the long-term marketable equity securities to fair value are included in other expense, net, in the condensed consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on long-term marketable securities are included in interest income, net.

Leases

The Company adopted Accounting Standard Codification ("ASC") Topic 842, *Leases* and determines if an arrangement is or contains a lease at contract inception. A right-of-use ("ROU") asset, representing the underlying asset during the lease term, and a lease liability, representing the payment obligation arising from the lease, are recognized on the condensed consolidated balance sheet at lease commencement based on the present value of the payment obligation. For operating leases, expense is recognized on a straight-line basis over the lease term. For finance leases, interest expense on the lease liability is recognized using the effective interest method and amortization of the ROU asset is recognized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet.

The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its incremental borrowing rate. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

As of March 31, 2022, the Company's leases had remaining terms of 0.17 years to 6.92 years, some of which include options to extend the lease term.

Recent Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*, which contains amendments that require annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model. The disclosures include (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. The amendments set forth in this ASU are effective for all entities for annual periods beginning after December 15, 2021. Early application of the amendments in this ASU is permitted. The amendments in this ASU should be applied either (1) prospectively to all transactions within the scope of the amendments that are reflected in financial statements at the date of initial application and new transactions that are entered into after the date of initial application or (2) retrospectively to those transactions. The Company adopted the standard prospectively on January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

In October 2021, the FASB issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires that an entity recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). At the acquisition date, an acquirer should account for the related revenue contracts in accordance with ASC 606 as if it had originated the contracts. The amendments set forth in this ASU are effective for fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. The amendments in this ASU should be applied prospectively to business combinations occurring on or after the effective date of the amendments. The Company early adopted the standard prospectively on January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)*: Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force), which contains amendments that clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The amendments set forth in this ASU are effective for all entities for annual periods beginning after December 15, 2021. Early application of the amendments in this ASU is permitted for all entities. The amendments in this ASU should be applied prospectively. The Company prospectively adopted the standard on January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

In October 2020, the FASB issued ASU No. 2020-10, *Codification Improvements*, which contains amendments that improve the consistency of the ASC by including all disclosure guidance in the appropriate Disclosure Section (Section 50). The FASB provided transition guidance for all the amendments in this ASU. The amendments in Sections B and C (Section A has been removed) of this ASU are effective for annual periods beginning after December 15, 2020 for public business entities. Early

application of the amendments in this ASU is permitted for public business entities for any annual or interim period for which financial statements have not been issued. The amendments in this ASU should be applied retrospectively. The Company adopted the standard on January 1, 2021. The adoption of the new standard did not have an impact on the Company's consolidated financial statements and disclosures.

### 3. NET LOSS PER SHARE

Basic and diluted net loss per share have been computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common share equivalents as their effect would have been antidilutive.

The following tables set forth the computation of the Company's basic and diluted net loss per share (in thousands, except shares and per share data):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Numerator:** | | |
| Net loss used to compute basic and diluted net loss per share | $ (19,648) | $ (687) |
| **Denominator:** | | |
| Weighted-average shares used to compute basic and diluted net loss per share | 53,015,459 | 51,181,160 |
| **Net loss per share:** | | |
| Basic and diluted | $ (0.37) | $ (0.01) |

The following potentially dilutive securities have been excluded from diluted net loss per share as of March 31, 2022 and 2021 because their effect would be antidilutive:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Shares of common stock subject to outstanding options | 2,091,422 | 2,592,281 |
| Shares of common stock subject to outstanding common stock warrants | 3,132 | 6,264 |
| Restricted stock units | 2,047,657 | 1,853,419 |
| Total common stock equivalents | 4,142,211 | 4,451,964 |

### 4. FAIR VALUE MEASUREMENTS

The Company records its financial assets and liabilities at fair value. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level 1: Inputs that include quoted prices in active markets for identical assets and liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table sets forth the Company's financial assets and liabilities, measured at fair value on a recurring basis, as of March 31, 2022 and December 31, 2021 (in thousands):

| | March 31, 2022 | | | |
|---|---|---|---|---|
| | Fair Value Measured Using | | | |
| | (Level 1) | (Level 2) | (Level 3) | Total Balance |
| **Assets** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 160,958 | $ — | $ — | $ 160,958 |
| Long-term marketable securities: | | | | |
| Corporate equity securities | 2,750 | — | — | 2,750 |
| Corporate debt securities | — | 500 | — | 500 |
| Total | $ 163,708 | $ 500 | $ — | $ 164,208 |
| **Liabilities** | | | | |
| Short-term liabilities: | | | | |
| Contingent consideration | $ — | $ — | $ 2,065 | $ 2,065 |
| Long-term liabilities: | | | | |
| Contingent consideration | — | — | 3,090 | 3,090 |
| Common stock warrant liability | — | — | 112 | 112 |
| | $ — | $ — | $ 5,267 | $ 5,267 |

| | December 31, 2021 | | | |
|---|---|---|---|---|
| | Fair Value Measured Using | | | |
| | (Level 1) | (Level 2) | (Level 3) | Total Balance |
| **Assets** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 335,107 | $ — | $ — | $ 335,107 |
| Long-term marketable securities: | | | | |
| Corporate equity securities | 3,257 | — | — | 3,257 |
| Corporate debt securities | — | 500 | — | 500 |
| Total | $ 338,364 | $ 500 | $ — | $ 338,864 |
| **Liabilities** | | | | |
| Short-term liabilities: | | | | |
| Contingent consideration | $ — | $ — | $ 2,114 | $ 2,114 |
| Long-term liabilities: | | | | |
| Contingent consideration | — | — | 3,227 | 3,227 |
| Common stock warrant liability | — | — | 139 | 139 |
| Total | $ — | $ — | $ 5,480 | $ 5,480 |

The following table presents the issuances, exercises, changes in fair value and reclassifications of the Company's Level 3 financial instruments that are measured at fair value on a recurring basis (in thousands):

| **Common Stock Warrant Liability and Contingent Consideration** | (Level 3) |
|---|---|
| Balance as of December 31, 2021 | $ 5,480 |
| Change in estimated fair value of common stock warrant liability | (27) |
| Change in estimated fair value of contingent consideration | 64 |
| Payments related to contingent consideration | (250) |
| Balance as of March 31, 2022 | $ 5,267 |

As of March 31, 2022, the Company had one investment in convertible preferred shares carried at cost. In the event the Company had to calculate the fair value of this investment, it would be based on Level 3 inputs. This investment is not considered material to the Company's condensed consolidated financial statements.

In determining fair value, the Company uses various valuation approaches within the fair value measurement framework. The valuation methodologies used for the Company's instruments measured at fair value and their classification in the valuation hierarchy are summarized below:

- *Money market funds* – Investments in money market funds are classified within Level 1. Money market funds are valued at the closing price reported by the fund sponsor from an actively traded exchange. At March 31, 2022 and December 31, 2021, money market funds were included as cash and cash equivalents in the condensed consolidated balance sheets.
- *Short-term marketable securities* – Investments in short-term marketable securities are classified within Level 2. The securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.
- *Long-term marketable equity and debt securities* – Investments in long-term marketable equity securities are classified within Level 1. The securities are recorded at fair value based on readily available quoted market prices in active markets. Investments in long-term marketable debt securities are classified within Level 2. The securities are recorded at fair value based on observable inputs for quoted prices for identical or similar assets in markets that are not active. Long-term marketable securities are located within other assets on the condensed consolidated balance sheets.
- *Contingent consideration* – Contingent consideration is classified within Level 3. Contingent consideration relates to asset acquisitions and business combinations. The Company recorded the estimate of the fair value of the contingent consideration based on its evaluation of the probability of the achievement of the contractual conditions that would result in the payment of the contingent consideration. Contingent consideration was estimated using the fair value of the milestones to be paid if the contingency is met multiplied by management's estimate of the probability of success at a discounted rate of 12% at March 31, 2022 and December 31, 2021. The significant input in the Level 3 measurement that is not supported by market activity is the Company's probability assessment of the achievement of the milestones. The value of the liability is subsequently remeasured to fair value at each reporting date, and the change in estimated fair value is recorded as a component of operating expenses until the milestones are paid, expire or are no longer achievable. Increases or decreases in the estimation of the probability percentage result in a directionally similar impact to the fair value measurement of the contingent consideration liability. The carrying amount of the contingent consideration liability represents its fair value.
- *Common stock warrant liability* – Common stock warrant liability is classified within Level 3. The Company utilizes intrinsic value to estimate the fair value of the warrants. The intrinsic value is computed as the difference between the fair value of the Company's common stock on the valuation date and the exercise price of the warrants. Increases (decreases) in the Company's stock price discussed above result in a directionally similar impact to the fair value of the common stock warrant liability. Prior to fiscal year 2022, the Company utilized a binomial lattice pricing model (the "Monte Carlo Simulation Model") which involves a market condition simulation to estimate the fair value of the warrants. The application of the Monte Carlo Simulation Model requires the use of a number of complex assumptions, including the Company's stock price, expected life of the warrants, stock price volatility determined from the Company's historical stock prices, and risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected life of the warrants. The change in valuation method does not have material financial impact.

*Common Stock Warrant Liability Valuation Assumptions Utilized at March 31, 2022 and December 31, 2021:*

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| **Private Placement Common Stock Warrant Liability** | | |
| Stock Price | $ 36.99 | $ 45.48 |
| Exercise Price | $ 1.12 | $ 1.12 |
| Remaining term (in years) | 1.04 | 1.28 |
| Volatility | N/A | 66.00 % |
| Risk-free interest rate | N/A | 0.49 % |

## 5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Restricted Cash

A reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets to the amount reported within the condensed consolidated statements of cash flows is shown in the table below (in thousands):

| | March 31, 2022 | December 31, 2021 | March 31, 2021 | December 31, 2020 |
|---|---|---|---|---|
| Cash and cash equivalents | $ 171,892 | $ 348,485 | $ 309,324 | $ 134,669 |
| Restricted cash | 214 | 211 | 269 | 270 |
| Total cash, cash equivalents, and restricted cash at the end of the period | $ 172,106 | $ 348,696 | $ 309,593 | $ 134,939 |

Marketable Securities

All short-term marketable securities were considered held-to-maturity at March 31, 2022. At March 31, 2022, some of the Company's short-term marketable securities were in an unrealized loss position. The Company determined that it had the positive intent and ability to hold until maturity all short-term marketable securities that have been in a continuous loss position, thus there was no recognition of any other-than-temporary impairment as of March 31, 2022. All short-term marketable securities with unrealized losses as of the balance sheet date have been in a loss position for less than twelve months. Contractual maturities of the short-term marketable securities were within one year or less at March 31, 2022.

The long-term marketable equity securities were recorded at fair market value at March 31, 2022 and December 31, 2021. The long-term marketable debt securities were considered available-for-sale at March 31, 2022 and December 31, 2021. The contractual maturity of the long-term marketable debt securities are less than three years.

The amortized cost, gross unrealized holding losses, and fair value of the Company's marketable securities by major security type at each balance sheet date are summarized in the tables below (in thousands):

| | March 31, 2022 | | |
|---|---|---|---|
| | Amortized Cost | Unrealized Holding Losses | Fair Value |
| Short-term marketable securities: | | | |
| Corporate debt securities | $ 147,330 | $ (523) | $ 146,807 |
| Total short-term marketable securities | 147,330 | (523) | 146,807 |
| Long-term marketable securities: | | | |
| Corporate equity securities | 5,000 | (2,250) | 2,750 |
| Corporate debt securities | 500 | — | 500 |
| Total long-term marketable securities | 5,500 | (2,250) | 3,250 |
| Total | $ 152,830 | $ (2,773) | $ 150,057 |

| | December 31, 2021 | | |
|---|---|---|---|
| | Amortized Cost | Unrealized Holding Losses | Fair Value |
| Long-term marketable securities: | | | |
| Corporate equity securities | $ 5,000 | $ (1,743) | $ 3,257 |
| Corporate debt securities | 500 | — | 500 |
| Total long-term marketable securities | $ 5,500 | $ (1,743) | $ 3,757 |

Contractual maturities of the marketable securities at each balance sheet date are as follows (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Within one year | $ 147,330 | $ — |
| After one year through five years | 500 | 500 |
| Total | $ 147,830 | $ 500 |

## 6. BUSINESS COMBINATIONS

The Transplant Pharmacy

In December 2021, the Company acquired TTP, a transplant focused pharmacy located in Mississippi. The Company acquired TTP with a combination of cash consideration paid upfront and contingent consideration with a fair value of $1.3 million. TTP provides individualized transplant pharmacy services for patients at multiple transplant centers located throughout the U.S.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Acquisition-related costs of $0.3 million were expensed as incurred, and classified as part of general and administrative expenses in the condensed consolidated statements of operations.

Goodwill of $5.5 million arising from the acquisition primarily consists of additional growth opportunities within the pharmacy sector. The integration of TTP into the Company's portfolio is expected to continue to increase the transplant ecosystem for patients and make medication more accessible. The Company estimated net deferred tax liabilities of approximately $0.6 million arising from temporary differences related to the assets acquired and liabilities assumed. None of the goodwill is expected to be deductible for income tax purposes. All of the goodwill has been assigned to the Company's existing operating segment.

The following table summarizes the fair value of the intangible asset acquired as of the acquisition date ($ in thousands):

| | Estimated Fair Value | Estimated Useful Life (Years) |
|---|---|---|
| Trademark | $ 2,080 | 10 |

The trademark acquired consists primarily of the TTP brand and markings. The fair value of the trademark was determined using the relief-from-royalty method under the income approach. This method considers the value of the asset to be the value of the royalty payments from which the Company is relieved due to its ownership of the asset. The royalty rate of 2% was used to estimate the fair value of the trademark.

A discount rate of 13.5% was utilized in estimating the fair value of the trademark.

The pro forma impact of the TTP acquisition is not material, and the results of operations of the acquisition have been included in the Company's condensed consolidated statements of operations from the respective acquisition date.

MedActionPlan

In November 2021, the Company acquired MedActionPlan, a New Jersey-based provider of medication safety, medication adherence and patient education. The Company acquired MedActionPlan with a combination of cash consideration paid upfront and contingent consideration with a fair value of $3.5 million. MedActionPlan is a leader in patient medication management for transplant patients and beyond.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Acquisition-related costs of $0.6 million associated with the acquisition were expensed as incurred, and classified as part of general and administrative expenses in the condensed consolidated statement of operations.

Goodwill of $4.9 million arising from the acquisition primarily consists of synergies from integrating the MedActionPlan technology with the current testing and digital solutions offered by the Company. The integration of MedActionPlan into centers with the Company's other software platforms will continue to increase the standard of care for transplant patient safety, increase efficiency and facilitate medication compliance. None of the goodwill is expected to be deductible for income tax purposes. All of the goodwill has been assigned to the Company's existing operating segment.

The following table summarizes the fair values of the intangible assets acquired as of the acquisition date ($ in thousands):

| | Estimated Fair Value | Estimated Useful Lives (Years) |
|---|---|---|
| Customer relationships | $ 2,590 | 10 |
| Developed technology | 1,090 | 10 |
| Trademarks | 80 | 5 |
| Total | $ 3,760 | |

Customer relationships acquired by the Company represent the fair value of future projected revenue that is expected to be derived from sales of MedActionPlan's products to existing customers. The customer relationships' fair value has been estimated utilizing a multi-period excess earnings method under the income approach, which reflects the present value of the

projected cash flows that are expected to be generated by the customer relationships, less charges representing the contribution of other assets to those cash flows that use projected cash flows with and without the intangible asset in place. The economic useful life was determined based on the distribution of the present value of the cash flows attributable to the intangible asset.

The acquired developed technology represents the fair value of MedActionPlan's proprietary software. The trademark acquired consists primarily of the MedActionPlan brand and markings. The fair value of both the developed technology and the trademark were determined using the relief-from-royalty method under the income approach. This method considers the value of the asset to be the value of the royalty payments from which the Company is relieved due to its ownership of the asset. The royalty rates of 15% and 1% were used to estimate the fair value of the developed technology and the trademark, respectively.

A discount rate of 40.0% was utilized in estimating the fair value of these three intangible assets.

The pro forma impact of the MedActionPlan acquisition is not material, and the results of operations of the acquisition have been included in the Company's condensed consolidated statements of operations from the respective acquisition date.

TransChart LLC

In January 2021, the Company acquired TransChart for cash. TransChart provides EMR software to hospitals throughout the U.S. to care for patients who have or may need an organ transplant. As a result of the acquisition, the Company recognized goodwill of $2.2 million and intangible assets of $2.0 million.

The pro forma impact of the TransChart acquisition is not material, and the results of operations of the acquisition have been included in the Company's condensed consolidated statements of operations from the respective acquisition date.

Combined Consideration Paid

The following table summarizes the consideration paid for TTP, MedActionPlan and TransChart, and the provisional amounts of the assets acquired and liabilities assumed recognized at their estimated fair value at the acquisition date ($ in thousands):

| | Total |
|---|---|
| **Consideration** | |
| Cash | $ 17,166 |
| Total consideration | $ 17,166 |
| | |
| **Recognized amounts of identifiable assets acquired and liabilities assumed** | |
| Current assets | $ 3,444 |
| Fixed assets | 23 |
| Identifiable intangible assets | 7,860 |
| Other assets | 2 |
| Current liabilities | (3,915) |
| Noncurrent liabilities | (2,883) |
| Total identifiable net assets acquired | 4,531 |
| Goodwill | 12,635 |
| Total consideration | $ 17,166 |

The allocation of the purchase price to assets acquired and liabilities assumed was based on the Company's best estimate of the fair value of such assets and liabilities as of the acquisition date.

## 7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

Goodwill is recorded when the purchase price of an acquisition exceeds the fair value of the net tangible and identified intangible assets acquired.

Goodwill is tested annually for impairment at the reporting unit level during the fourth quarter or earlier upon the occurrence of certain events or substantive changes in circumstances. There were no indicators of impairment in the three months ended March 31, 2022. The balance of the Company's goodwill was $37.0 million as of March 31, 2022 and December 31, 2021.

Intangible Assets

The following table presents details of the Company's intangible assets as of March 31, 2022 ($ in thousands):

| | March 31, 2022 | | | | |
|---|---|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Foreign Currency Translation | Net Carrying Amount | Weighted Average Remaining Useful Life (In Years) |
| **Intangible assets with finite lives:** | | | | | |
| Acquired and developed technology | $ 35,874 | $ (12,905) | $ (1,706) | $ 21,263 | 8.0 |
| Customer relationships | 21,898 | (6,396) | (1,407) | 14,095 | 9.6 |
| Commercialization rights | 10,579 | (2,309) | — | 8,270 | 7.4 |
| Trademarks and tradenames | 4,540 | (1,079) | (190) | 3,271 | 9.2 |
| Other | 250 | (250) | — | — | 0.0 |
| **Total intangible assets with finite lives** | $ 73,141 | $ (22,939) | $ (3,303) | $ 46,899 | |
| Acquired in-process technology | 1,250 | — | — | 1,250 | |
| **Total intangible assets** | $ 74,391 | $ (22,939) | $ (3,303) | $ 48,149 | |

The following table presents details of the Company's intangible assets as of December 31, 2021 ($ in thousands):

| | December 31, 2021 | | | | |
|---|---|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Foreign Currency Translation | Net Carrying Amount | Weighted Average Remaining Useful Life (In Years) |
| **Intangible assets with finite lives:** | | | | | |
| Acquired and developed technology | $ 35,874 | $ (12,088) | $ (1,513) | $ 22,273 | 8.1 |
| Customer relationships | 21,898 | (6,024) | (1,210) | 14,664 | 9.9 |
| Commercialization rights | 10,579 | (2,030) | — | 8,549 | 7.6 |
| Trademarks and tradenames | 4,540 | (988) | (155) | 3,397 | 9.5 |
| Other | 250 | (188) | — | 62 | 0.2 |
| **Total intangible assets with finite lives** | $ 73,141 | $ (21,318) | $ (2,878) | $ 48,945 | |
| Acquired in-process technology | 1,250 | — | — | 1,250 | |
| **Total intangible assets** | $ 74,391 | $ (21,318) | $ (2,878) | $ 50,195 | |

Acquisition of Intangible Assets

In June 2021, the Company acquired commercialization rights in an exclusive partnership for comprehensive data analytics in relation to NGS-based metagenomics testing for infectious diseases. This is included within Commercialization rights as of March 31, 2022.

In June 2021, the Company acquired the Transplant Hero patient application. The patient application is included in Acquired and developed technology as of March 31, 2022.

In the fourth quarter of 2021, acquisition of intangible assets increased $13.4 million primarily from business combinations. These acquisitions included $4.7 million of Acquired and developed technology, $2.5 million of Commercialization rights, $3.7 million of Customer relationships, $2.2 million of Trademarks and tradenames and $0.3 million of Other intangible assets.

Amortization of Intangible Assets

Amortization expense was $1.6 million and $1.3 million for the three months ended March 31, 2022 and 2021, respectively. For the three months ended March 31, 2022, expenses of $0.3 million, $0.5 million, $0.2 million and $0.6 million were amortized to cost of testing services, cost of product, cost of patient and digital solutions and sales and marketing, respectively. For the three months ended March 31, 2021, expenses of $0.3 million, $0.5 million, $0.1 million and $0.4 million were amortized to cost of testing services, cost of product, cost of patient and digital solutions and sales and marketing, respectively.

Intangible assets are carried at cost less accumulated amortization. Amortization expenses are recorded to cost of testing services, cost of product, cost of patient and digital solutions, and sales and marketing expenses in the condensed consolidated statements of operations.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of March 31, 2022 (in thousands):

| Years Ending December 31, | Cost of Testing Services | Cost of Product | Cost of Patient and Digital Solutions | Sales and Marketing | Total |
|---|---|---|---|---|---|
| Remainder of 2022 | $ 987 | $ 1,362 | $ 709 | $ 1,630 | $ 4,688 |
| 2023 | 1,316 | 1,817 | 945 | 2,163 | 6,241 |
| 2024 | 1,316 | 1,817 | 709 | 2,163 | 6,005 |
| 2025 | 1,316 | 1,817 | 540 | 2,163 | 5,836 |
| 2026 | 1,316 | 772 | 540 | 2,160 | 4,788 |
| Thereafter | 4,140 | 4,153 | 1,720 | 9,328 | 19,341 |
| Total future amortization expense | $ 10,391 | $ 11,738 | $ 5,163 | $ 19,607 | $ 46,899 |

## 8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Finished goods | $ 3,274 | $ 3,911 |
| Work in progress | 3,495 | 2,828 |
| Raw materials | 11,443 | 10,447 |
| Total inventory | $ 18,212 | $ 17,186 |

Accrued and Other Liabilities

Accrued and other liabilities consisted of the following (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Clinical studies | $ 12,904 | $ 10,653 |
| Professional fees | 7,983 | 5,780 |
| Deferred revenue | 3,941 | 4,208 |
| Short-term lease liability | 3,697 | 3,958 |
| Accrued royalty | 3,164 | 1,664 |
| Contingent consideration | 2,065 | 2,114 |
| Deferred payments for intangible assets | 2,000 | 2,000 |
| Test sample processing fees | 1,950 | 1,197 |
| Capital expenditures | 1,686 | 2,612 |
| Other accrued expenses | 5,507 | 3,736 |
| Total accrued and other liabilities | $ 44,897 | $ 37,922 |

CMS Accelerated and Advance Payment Program for Medicare Providers

On March 27, 2020, the U.S. government enacted the CARES Act. Pursuant to the CARES Act, CMS expanded its Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS was authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submitted a request to the appropriate Medicare Administrative Contractor and met the required qualifications. During April 2020, the Company received an advance payment from CMS of approximately $20.5 million and recorded the payment as Deferred revenue - CMS advance payment on the Company's condensed consolidated balance sheet. During December 2020, the Company reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021.

## 9. COMMITMENTS AND CONTINGENCIES

### Leases

The Company leases its operating and office facilities for various terms under long-term, non-cancelable operating lease agreements in South San Francisco, California; Brisbane, California; Columbus, Ohio; West Chester, Pennsylvania; Flowood, Mississippi; Gaithersburg, Maryland; Fremantle, Australia; and Stockholm, Sweden.

The Company's facility leases expire at various dates through 2029. In the normal course of business, it is expected that these leases will be renewed or replaced by leases on other properties.

As of March 31, 2022, the carrying value of the ROU asset was $17.1 million. The related current and non-current liabilities as of March 31, 2022 were $3.7 million and $16.7 million, respectively. The current and non-current lease liabilities are included in accrued and other current liabilities and operating lease liability, less current portion, respectively, in the condensed consolidated balance sheets.

The following table summarizes the lease cost for the three months ended March 31, 2022 and 2021 (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Operating lease cost | $ 1,413 | $ 1,205 |
| Finance lease cost | — | 30 |
| Total lease cost | $ 1,413 | $ 1,235 |

Finance lease cost includes interest from the lease liability and amortization of the ROU asset.

| | March 31, 2022 |
|---|---|
| Other information: | |
| Weighted-average remaining lease term - Operating leases (in years) | 5.83 |
| Weighted-average discount rate - Operating leases (%) | 10.0 % |

Maturities of operating lease liabilities as of March 31, 2022 are as follows (in thousands):

| Year Ending December 31, | Operating Leases |
|---|---|
| Remainder of 2022 | $ 4,238 |
| 2023 | 4,372 |
| 2024 | 4,315 |
| 2024 | 4,040 |
| 2025 | 3,196 |
| Thereafter | 7,140 |
| Total lease payments | 27,301 |
| Less imputed interest | 6,875 |
| Present value of future minimum lease payments | 20,426 |
| Less operating lease liability, current portion | 3,697 |
| Operating lease liability, long-term portion | $ 16,729 |

### Royalty Commitments

The Board of Trustees of the Leland Stanford Junior University (“Stanford”)

In June 2014, the Company entered into a license agreement with Stanford (the “Stanford License”), which granted the Company an exclusive license to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Under the terms of the Stanford License, the Company is required to pay an annual license maintenance fee, six milestone payments and royalties in the low single digits of net sales of products incorporating the licensed technology.

Illumina

On May 4, 2018, the Company entered into a license agreement with Illumina (the “Illumina Agreement”). The Illumina Agreement requires the Company to pay royalties in the mid-single to low-double digits on sales of products covered by the Illumina Agreement.

**Cibiltech Commitments**

Pursuant to that certain license and commercialization agreement that the Company entered into with Cibiltech SAS (“Cibiltech”) effective April 30, 2019, the Company will share an agreed-upon percentage of revenue with Cibiltech, if and when revenues are generated from iBox.

**Other Commitments**

Pursuant to the Illumina Agreement, the Company has agreed to minimum purchase commitments of finished products and raw materials from Illumina through 2023.

**Litigation and Indemnification Obligations**

In response to the Company's false advertising suit filed against Natera Inc. (“Natera”), on April 10, 2019, Natera filed a counterclaim against the Company on February 18, 2020, in the U.S. District Court for the District of Delaware (the “Court”) alleging the Company made false and misleading claims about the performance capabilities of AlloSure. The suit seeks injunctive relief and unspecified monetary relief. On September 30, 2020, Natera requested leave of Court to amend its counterclaims to include additional allegations regarding purportedly false claims the Company made with respect to AlloSure, and the Court granted Natera’s request. The trial commenced on March 7, 2022 and concluded on March 14, 2022, with the jury awarding the Company $44.9 million in damages, comprised of $21.2 million in compensatory damages and $23.7 million in punitive damages. The Company will not record the settlement until the post-trial motion practice has concluded.

In addition, in response to the Company's patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against the Company on January 13, 2020, in the Court alleging, among other things, that AlloSure infringes Natera’s U.S. Patent 10,526,658. On March 25, 2020, Natera filed an amendment to the suit alleging, among other things, that AlloSure also infringes Natera’s U.S. Patent 10,597,724. The suit seeks a judgment that the Company has infringed Natera’s patents, an order preliminarily and permanently enjoining the Company from any further infringement of such patents and unspecified damages. Trial is currently scheduled for July 24, 2023. The Company intends to defend both of these matters vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail. The Company has not recorded any liabilities for these suits.

United States Department of Justice and United States Securities and Exchange Commission Investigations

As previously disclosed, in 2021, the Company received a civil investigative demand (“CID”) from the United States Department of Justice ("DOJ") requesting that the Company produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to the Company's kidney testing and phlebotomy services, and a subpoena from the United States Securities and Exchange Commission (“SEC”) in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of the Company's accounting and public reporting practices. The Company also received an information request from a state regulatory agency and may receive additional requests for information from the DOJ, SEC, or other regulatory and governmental agencies regarding similar or related subject matters. The Company does not believe that the CID, the SEC subpoena or the state regulatory agency information request raise any issues regarding the safety or efficacy of any of the Company's products or services and are cooperating fully with the investigations. Although the Company remains committed to compliance with all applicable laws and regulations, it cannot predict the outcome of the DOJ or SEC investigations, the state regulatory agency information request, or any other requests or investigations that may arise in the future regarding these or other subject matters.

From time to time, the Company may become involved in litigation and other legal actions. The Company estimates the range of liability related to any pending litigation where the amount and range of loss can be estimated. The Company records its best estimate of a loss when the loss is considered probable. Where a liability is probable and there is a range of estimated loss with no best estimate in the range, the Company records a charge equal to at least the minimum estimated liability for a loss contingency when both of the following conditions are met: (i) information available prior to issuance of the condensed consolidated financial statements indicates that it is probable that a liability had been incurred at the date of the condensed consolidated financial statements, and (ii) the range of loss can be reasonably estimated.

**10. 401(K) PLAN**

The Company sponsors a 401(k) defined contribution plan (the "401(k) Plan") covering all U.S. employees under the Internal Revenue Code of 1986, as amended. Employee contributions to the 401(k) Plan are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. The Company incurred expenses related to

contributions to the 401(k) Plan of $0.7 million and $0.5 million for the three months ended March 31, 2022 and 2021, respectively.

**11. WARRANTS**

The Company issues common stock warrants in connection with debt or equity financings to lenders, placement agents and investors. Issued warrants are considered standalone financial instruments and the terms of each warrant are analyzed for equity or liability classification in accordance with U.S. GAAP. Warrants that are classified as liabilities usually have various features that would require net-cash settlement by the Company. Warrants that are not liabilities, derivatives and/or meet the exception criteria are classified as equity. Warrants liabilities are remeasured at fair value at each period end with changes in fair value recorded in the condensed consolidated statements of operations until expired or exercised. Warrants that are classified as equity are valued at their relative fair value on the date of issuance, recorded in additional paid in capital and not remeasured.

In the three months ended March 31, 2022 and 2021, no warrants to purchase shares of common stock were exercised.

As of March 31, 2022, outstanding warrants to purchase common stock were:

| | Classified as | Original Term | Exercise Price | Number of Shares Underlying Warrants |
|---|---|---|---|---|
| Original issue date: | | | | |
| April 2016 | Liability | 7 years | $ 1.12 | 3,132 |
| | | | | 3,132 |

**12. STOCK INCENTIVE PLANS**

Stock Options and Restricted Stock Units ("RSU")

The following table summarizes option and RSU activity under the Company's 2014 Equity Incentive Plan, 2016 Inducement Equity Incentive Plan, and 2019 Inducement Equity Incentive Plan, and related information:

| | Shares Available for Grant | Stock Options Outstanding | Weighted-Average Exercise Price | Number of RSU Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|---|---|---|
| Balance—December 31, 2021 | 2,066,529 | 1,863,633 | $ 29.33 | 2,047,657 | $ 50.21 |
| Additional shares authorized | 2,116,934 | — | — | — | — |
| Common stock awards for services | (1,249) | — | — | — | — |
| RSUs granted | (474,000) | — | — | 474,000 | 39.81 |
| RSUs vested | — | — | — | (100,456) | 52.38 |
| Options granted | (341,800) | 341,800 | 41.21 | — | — |
| Options exercised | — | (69,993) | 22.83 | — | — |
| Repurchase of common stock under employee incentive plans | 35,637 | — | — | — | — |
| RSUs forfeited | 78,687 | — | — | (78,687) | 52.94 |
| Options forfeited | 40,268 | (40,268) | 37.13 | — | — |
| Options expired | 3,750 | (3,750) | 33.10 | — | — |
| Balance—March 31, 2022 | 3,524,756 | 2,091,422 | $ 31.33 | 2,342,514 | $ 47.92 |

The total intrinsic value of options exercised was $1.0 million and $9.1 million for the three months ended March 31, 2022 and 2021, respectively.

As of March 31, 2022, the total intrinsic value of outstanding RSUs was approximately $86.6 million and there were $87.5 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.99 years.

Options outstanding that have vested and are expected to vest at March 31, 2022 are as follows:

| | Number of Shares Issued (In thousands) | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value (In thousands) |
|---|---|---|---|---|
| Vested | 1,038 | $ 22.91 | 6.52 | $ 16,861 |
| Expected to vest | 976 | 39.76 | 8.62 | 4,644 |
| Total | 2,014 | | | $ 21,505 |

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at March 31, 2022 for stock options that were in-the-money.

The total fair value of options that vested during the three months ended March 31, 2022 was $4.0 million. As of March 31, 2022, there were approximately $24.8 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 2.82 years.

2014 Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan (the "ESPP"), under which employees can purchase shares of its common stock based on a percentage of their compensation, but not greater than 15% of their respective earnings; provided, however, an eligible employee's right to purchase shares of the Company's common stock may not accrue at a rate which exceeds $25,000 of the fair market value of such shares for each calendar year in which such rights are outstanding. The ESPP has consecutive offering periods of approximately six months in length. The purchase price per share must be equal to the lower of 85% of the fair value of the common stock on the first day of the offering period or on the exercise date.

During the offering period in 2021 that ended on December 31, 2021, 25,852 shares were purchased pursuant to the ESPP for aggregate proceeds of $1.0 million from the issuance of such shares, which occurred on January 6, 2022.

Valuation Assumptions

The estimated fair values of employee stock options and ESPP shares were estimated using the Black-Scholes option pricing model based on the following weighted average assumptions:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Employee stock options** | | |
| Expected term (in years) | 6.0 | 6.0 |
| Expected volatility | 76.93% | 77.69% |
| Risk-free interest rate | 1.65% | 0.68% |
| Expected dividend yield | —% | —% |
| **Employee stock purchase plan** | | |
| Expected term (in years) | 0.5 | 0.5 |
| Expected volatility | 67.79% | 53.10% |
| Risk-free interest rate | 1.06% | 0.09% |
| Expected dividend yield | —% | —% |

Risk-free Interest Rate: The Company based the risk-free interest rate over the expected term of the award based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of grant.

Volatility*:* The Company used an average historical stock price volatility of its own stock.

Expected Term: The expected term represents the period for which the Company's stock-based compensation awards are expected to be outstanding and is based on analyzing the vesting and contractual terms of the awards and the holders' historical exercise patterns and termination behavior.

Expected Dividends*:* The Company has not paid and does not anticipate paying any dividends in the near future.

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense relating to employee and non-employee stock-based awards for the three months ended March 31, 2022 and 2021, included in the condensed consolidated statements of operations as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cost of testing services | $ 19 | $ 395 |
| Cost of product | 128 | 76 |
| Cost of patient and digital solutions | 192 | 108 |
| Research and development | 2,190 | 1,358 |
| Sales and marketing | 3,123 | 1,659 |
| General and administrative | 4,982 | 2,951 |
| Total | $ 10,634 | $ 6,547 |

No tax benefit was recognized related to stock-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. In addition, no amounts of stock-based compensation expense were capitalized for the periods presented.

**13. INCOME TAXES**

The Company's effective tax rate may vary from the U.S. federal statutory tax rate due to the change in the mix of earnings in tax jurisdictions with different statutory rates, benefits related to tax credits, and the tax impact of non-deductible expenses and other permanent differences between income before income taxes and taxable income.

For the three months ended March 31, 2022 and 2021, the Company recorded an income tax benefit of $12.0 thousand and $0.3 million, respectively. The income tax benefit of $12.0 thousand is primarily attributable to the recognition of deferred tax assets from foreign losses. The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative, including (i) cumulative results of operations in recent years, (ii) sources of recent losses, (iii) estimates of future taxable income, and (iv) the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its U.S. net deferred tax assets. The Company has also placed a valuation allowance on the net deferred tax assets of its Australian operations. Accordingly, the U.S. and Australian net deferred tax assets have been offset by a full valuation allowance.

**14. SEGMENT REPORTING**

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the Company's Chief Operating Decision Maker ("CODM"), or decision making group, whose function is to allocate resources to and assess the performance of the operating segments. The Company has identified its Chief Executive Officer as the CODM. In determining its reportable segments, the Company considered the markets and types of customers served and the products or services provided in those markets. The Company operates in a single reportable segment.

Revenues by geographic regions are based upon the customers' ship-to address for product revenue and the region of testing for testing services revenue. The following table summarizes reportable revenues by geographic regions (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Testing services revenue** | | |
| United States | $ 66,223 | $ 59,021 |
| Rest of World | 221 | 260 |
| | $ 66,444 | $ 59,281 |
| **Product revenue** | | |
| United States | $ 3,613 | $ 2,495 |
| Europe | 2,242 | 2,252 |
| Rest of World | 933 | 1,031 |
| | $ 6,788 | $ 5,778 |
| **Patient and digital solutions revenue** | | |
| United States | $ 6,153 | $ 2,288 |
| Europe | 10 | 31 |
| Rest of World | 21 | 22 |
| | $ 6,184 | $ 2,341 |
| | | |
| Total United States | $ 75,989 | $ 63,804 |
| Total Europe | $ 2,252 | $ 2,283 |
| Total Rest of World | $ 1,175 | $ 1,313 |
| | | |
| Total | $ 79,416 | $ 67,400 |

The following table summarizes long-lived assets, consisting of property and equipment, net, by geographic regions (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Long-lived assets: | | |
| United States | $ 26,986 | $ 21,444 |
| Europe | 442 | 403 |
| Rest of World | 136 | 197 |
| Total | $ 27,564 | $ 22,044 |

**15. SUBSEQUENT EVENTS**

*At-the-Market Equity Offering*

On April 14, 2022, the Company entered into a sales agreement (the "Sales Agreement") with Jefferies, LLC as sales agent ("Jefferies"), pursuant to which the Company may offer and sell, from time to time, through Jefferies, up to $200.0 million in shares of its common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Jefferies is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold through Jefferies under the Sales Agreement. Any shares of common stock offered and sold pursuant to the Sales Agreement will be issued and sold pursuant to the Company's Registration Statement on Form S-3ASR (File No. 333-239049), filed with the SEC on June 9, 2020, including a base prospectus dated June 9, 2020, and a prospectus supplement dated April 14, 2022.

*Olymbios Matter*

On April 15, 2022, a complaint was filed by Michael Olymbios against the Company in the Superior Court of the State of California for the County of San Mateo (the "Court"). The complaint alleges that the Company failed to pay certain fees and costs required to continue an arbitration proceeding against Dr. Olymbios, and that the Company has defamed Dr. Olymbios. Dr. Olymbios also seeks to void restrictive covenants previously agreed to by him in favor of the Company and to recover damages purportedly incurred by Dr. Olymbios. The Company filed a motion to compel arbitration and dismiss the case. On

April 25, 2022, the Court granted the Company's *ex parte* application to stay the case and advance the hearing date to June 10, 2022 for the motion to compel arbitration and dismiss. In the event the case continues, the Company intends to defend itself vigorously. The Company believes it has good and substantial defenses to the claims alleged in the suit, but there is no guarantee that the Company will prevail if the case continues. The Company has not recorded any liabilities for this suit.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and related notes included elsewhere in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission, or the SEC, on February 24, 2022.*

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "should," "would," "project," "plan," "target," "contemplate," "predict," "expect" and the negative and plural forms of these words and similar expressions are intended to identify forward-looking statements.

These forward-looking statements may include, but are not limited to, statements concerning the following:

- the potential impact to our business, revenue, financial condition and employees, including disruptions to our testing services, laboratories, clinical trials, supply chain and operations, due to the COVID-19 global pandemic;
- our ability to generate revenue and increase the commercial success of our current and future testing services, products and patient and digital solutions;
- our ability to obtain, maintain and expand reimbursement coverage from payers for our current and other future testing services, if any;
- our plans and ability to continue updating our testing services, products and patient and digital solutions to maintain our leading position in transplantations;
- the outcome or success of our clinical trial collaborations and registry studies, including Kidney Allograft Outcomes AlloSure Registry, or K-OAR, the Outcomes of KidneyCare™ on Renal Allografts registry study, or OKRA, and the Surveillance HeartCare Outcomes Registry, or SHORE;
- the favorable review of our testing services and product offerings, and our future solutions, if any, in peer-reviewed publications;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;
- anticipated trends and challenges in our business and the markets in which we operate;
- our dependence on certain of our suppliers, service providers and other distribution partners;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to retain key members of our management team;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to expand internationally;
- our compliance with federal, state and foreign regulatory requirements;
- our ability to protect and enforce our intellectual property rights, our strategies regarding filing additional patent applications to strengthen our intellectual property rights, and our ability to defend against intellectual property claims that may be brought against us;
- our ability to successfully assert, defend against or settle any litigation brought by or against us or other legal matters or disputes; and
- our ability to comply with the requirements of being a public company.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled "Risk Factors" in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 24, 2022. Moreover, we operate in a very competitive and

rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially and adversely from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the SEC as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all forward-looking statements by these cautionary statements.

**Overview and Recent Highlights**

CareDx, Inc., or collectively, the Company, we, us and our, is a leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. We offer testing services, products, and digital healthcare solutions along the pre- and post-transplant patient journey, and we are a leading provider of genomics-based information for transplant patients.

***Highlights for the Three Months Ended March 31, 2022 and Recent Highlights***

- Achieved total revenue of $79.4 million for the three months ended March 31, 2022, increasing 18% year-over-year
- Provided approximately 42,600 AlloSure and AlloMap patient results in the quarter, with March being our highest ever month of testing volume for Heart and Kidney Testing Services
- Showcased scientific leadership with over 25 oral presentations and abstracts at the International Society of Heart and Lung Transplantation including real-world, multi-center, prospective, long-term SHORE data
- Incorporated Tx Access into the AlloCare app to help pre-transplant patients navigate the waitlist process as we digitally connect patients across the patient journey
- Helped ensure that the transplant community receives accurate information about our tests after a jury found that Natera (Nasdaq: NTRA) made false superiority claims in its advertising, and awarded CareDx monetary damages totaling $44.9 million
- Announced the availability of XenoSure™ and XenoMap™, the world's first surveillance solutions for investigational use in xenotransplantation research and post-xenotransplant clinical monitoring

***Testing Services***

***Kidney***

AlloSure Kidney, our transplant surveillance solution, was commercially launched in October 2017 and is our donor-derived cell-free DNA, or dd-cfDNA offering built on a next generation sequencing, or NGS, platform. In transplantation, more than 100 papers from over 50 studies globally have shown the value of dd-cfDNA in the management of solid organ transplantation. AlloSure Kidney is able to discriminate dd-cfDNA from recipient-cell-free DNA, targeting polymorphisms between donor and recipient. This SNP approach across all the somatic chromosomes is specifically designed for transplantation, allowing a scalable, high-quality test to differentiate dd-cfDNA.

AlloSure Kidney has received positive coverage decisions for reimbursement from Medicare. The Medicare reimbursement rate for AlloSure Kidney is $2,841. AlloSure Kidney has received positive coverage decisions from several commercial payers, and is reimbursed by other private payers on a case-by-case basis.

Multiple studies have demonstrated that significant allograft injury can occur in the absence of changes in serum creatinine. Thus, clinicians have limited ability to detect injury early and intervene to prevent long-term damage using this marker. While histologic analysis of the allograft biopsy specimen remains the standard method used to assess injury and differentiate rejection from other injury in kidney transplants, as an invasive test with complications, repetitive biopsies are not well tolerated.

AlloSure Kidney provides a non-invasive test, assessing allograft injury that enables more frequent, quantitative and safer assessment of allograft rejection and injury status. Beyond allograft rejection, the assessment of molecular inflammation has shown further utility in the assessment of proteinuria, the formation of De Novo donor specific antibodies, or DSAs, and as a surrogate predictive measure of estimated glomerular filtration rate, or eGFR, decline. Monitoring of graft injury through AlloSure Kidney allows clinicians to optimize allograft biopsies, identify allograft injury and guide immunosuppression management more accurately.

Since the analytical validation paper in the Journal of Molecular Diagnostics in 2016 before the commercial launch of AlloSure Kidney, there has been an increasing body of evidence supporting the use of AlloSure Kidney dd-cfDNA in the assessment and surveillance of kidney transplants. Bloom et al evaluated 102 kidney recipients and demonstrated that dd-cfDNA levels could discriminate accurately and non-invasively distinguish rejection from other types of graft injury. In contrast, serum creatinine has area under the curve of 50%, showing no significant difference between patients with and without rejection. Multiple publications and abstracts have shown AlloSure Kidney's value in the management of BK viremia, as well as numerous pathologies that cause molecular inflammation and injury such as DSAs and eGFR decline. Most recently its utility in the assessment of T-cell mediated rejection (TCMR) 1A and borderline rejection was published in the American Journal of Transplant, or AJT, and the outcomes of 1,000 patients was published in Kidney International.

The prospective multicenter trial, the K-OAR study, has enrolled over 1,700 patients, with plans to survey patients with AlloSure Kidney for 3 years and provide further clinical utility of AlloSure Kidney in the surveillance of kidney transplant recipients.

***KidneyCare***

KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the predictive artificial intelligence technology of iBox in one surveillance solution. We have not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or iBox.

In September 2019, we announced the enrollment of the first patient in the OKRA study, which is an extension of the K-OAR study. OKRA is a prospective, multi-center, observational registry of patients receiving KidneyCare for surveillance. Combined with K-OAR, 3,000 patients will be enrolled into the study.

***Heart***

AlloMap Heart is a gene expression test that helps clinicians monitor and identify heart transplant recipients with stable graft function who have a low probability of moderate-to-severe acute cellular rejection. Since 2008, we have sought to expand the adoption and utilization of our AlloMap Heart solution through ongoing studies to substantiate the clinical utility and actionability of AlloMap Heart, secure positive reimbursement decisions from large private and public payers, develop and enhance our relationships with key members of the transplant community, including opinion leaders at major transplant centers, and explore opportunities and technologies for the development of additional solutions for post-transplant surveillance.

We believe the use of AlloMap Heart, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant, can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and may help to determine the appropriate dosage levels of immunosuppressants. In 2008, AlloMap Heart received 510(k) clearance from the U.S. Food and Drug Administration for marketing and sale as a test to aid in the identification of heart transplant recipients, who have a low probability of moderate/severe acute cellular rejection at the time of testing, in conjunction with standard clinical assessment.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 1, 2006. The Medicare reimbursement rate for AlloMap Heart is currently $3,240.

AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

In October 2020, we received a final Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, our Medicare Administrative Contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently $2,753. AlloSure Heart has received positive coverage decisions from several commercial payers.

We have also successfully completed several landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap Heart for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap Heart based on our Cardiac Allograft Rejection Gene Expression Observational (Deng, M. et al., Am J Transplantation 2006) study, which was published in the AJT. A subsequent clinical utility trial, Invasive Monitoring Attenuation through Gene Expression (Pham MX et al., N. Eng. J. Med., 2010), published in The New England Journal of Medicine, demonstrated that clinical outcomes in recipients managed with AlloMap Heart surveillance were equivalent (non-

inferior) to outcomes in recipients managed with biopsies. The results of our clinical trials have also been presented at major medical society congresses. AlloMap Heart is now recommended as part of the ISHLT (International Society for Heart and Lung Transplantation) guidelines.

***HeartCare***

HeartCare includes the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from two complementary measures: (i) AlloMap Heart – a measure of immune activation, and (ii) AlloSure Heart – a measure of graft injury.

Clinical validation data from the Donor-Derived Cell-Free DNA-Outcomes AlloMap Registry (NCT02178943), or D-OAR, was published in the AJT in 2019. D-OAR was an observational, prospective, multicenter study to characterize the AlloSure Heart dd-cfDNA in a routine, clinical surveillance setting with heart transplant recipients. The D-OAR study was designed to validate that plasma levels of AlloSure Heart dd-cfDNA can discriminate acute rejection from no rejection, as determined by endomyocardial biopsy criteria.

HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, acute cellular rejection and antibody mediated rejection. In September 2018, we initiated the SHORE study. SHORE is a prospective, multi-center, observational, registry of patients receiving HeartCare for surveillance. Patients enrolled in SHORE will be followed for 5 years with collection of clinical data and assessment of 5-year outcomes.

***Lung***

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. One of these studies, launched in April 2020, is the ALARM study, or AlloSure Lung Allograft Remote Monitoring, with Johns Hopkins University, where the impact of AlloSure Lung combined with RemoTraC will be measured. AlloSure Lung applies proprietary NGS technology to measure dd-cfDNA from the donor lung in the recipient bloodstream to monitor graft injury. In June 2020, we submitted an application to the Palmetto MolDx Technology Assessment program seeking coverage and reimbursement for AlloSure Lung. In October 2021, we launched AlloSure Lung as part of the CHEST 2021 Annual Meeting. We have gained early adoption with some commercial payers.

***Cellular Therapy***

In April 2020, we initiated a research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy. AlloCell is being commercialized through research agreements with biopharma companies developing cell therapies. In 2021, we executed multiple additional agreements with biopharma therapeutics companies to use AlloCell in research and clinical studies.

In July 2021, we launched the Assessing Chimerism and Relapse of Bone marrow/ HCT transplant using AlloHeme Testing, or ACROBAT Study. The ACROBAT Study is a prospective, multicenter, observational cohort study to evaluate the use of AlloHeme, a microchimerism NGS tool to predict post-transplant relapse in patients with allogeneic hematopoietic cell transplants, or HCT.

***Products***

We develop, manufacture, market and sell products that increase the chance of successful transplants by facilitating a better match between a solid organ or stem cell donor and a recipient, and help to provide post-transplant surveillance of these recipients.

QTYPE enables Human Leukocyte Antigen, or HLA, typing at a low to intermediate resolution for samples that require a fast turn-around-time and uses real-time polymerase chain reaction, or PCR, methodology. Olerup SSP is used to type HLA alleles based on the sequence specific primer, or SSP, technology.

On May 4, 2018, we entered into a license and collaboration agreement with Illumina, Inc., or Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS products and technologies for use in transplantation diagnostic testing.

On June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line. TruSight HLA is a high-resolution solution that uses NGS methodology. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines in the field of bone marrow and solid organ transplantation on diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients.

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and we received CE mark authorization on January 10, 2020. Our ability to increase the clinical uptake for AlloSeq cfDNA will be a result of multiple factors, including local clinical education, customer lab technical proficiency and levels of country-specific reimbursement.

Also in September 2019, we commercially launched AlloSeq Tx, the first of its kind NGS high-resolution HLA typing solution utilizing hybrid capture technology. This technology enables the most comprehensive sequencing, covering more of the HLA genes than other solutions on the market and adding coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx has simple NGS workflow, with a single tube for processing and steps to reduce errors. AlloSeq Tx 17 received CE mark authorization on May 15, 2020.

In June 2020, we commercially launched AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients. This technology has the potential to provide better sensitivity and data analysis compared to current solutions on the market.

In March 2021, we acquired certain assets of BFS Molecular S.R.L., or BFS Molecular, a software company focused on NGS-based patient testing solutions. BFS Molecular brings extensive software and algorithm development capabilities for NGS transplant surveillance products.

***Patient and Digital Solutions***

In 2019, we began providing digital solutions to transplant centers following the acquisitions of Ottr, Inc., or Ottr, and XynManagement, Inc., or XynManagement.

On May 7, 2019, we acquired 100% of the outstanding common stock of Ottr. Ottr was formed in 1993 and is a leading provider of transplant patient management software, or the Ottr software, which provides comprehensive solutions for transplant patient management. The Ottr software enables integration with electronic medical records, or EMR, systems, including Cerner and Epic, providing patient surveillance management tools and outcomes data to transplant centers.

On August 26, 2019, we acquired 100% of the outstanding common stock of XynManagement. XynManagement provides two unique solutions, XynQAPI software, or XynQAPI and XynCare. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients reporting. XynCare includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

In September 2020 we launched AlloCare, a mobile app that provides a patient-centric resource for transplant recipients to manage medication adherence, coordinate with Patient Care Managers for AlloSure scheduling and measure health metrics.

In January 2021, we acquired TransChart LLC, or TransChart. TransChart provides EMR software to hospitals throughout the United States to care for patients who have or may need an organ transplant. As part of our acquisition of TransChart in January 2021, we acquired Tx Access, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs, closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

In June 2021, we acquired the Transplant Hero patient application. The application helps patients manage their medications through alarms and interactive logging of medication events.

Also in June 2021, we entered into a strategic agreement with OrganX to develop clinical decision support tools across the transplant patient journey. Together, we and OrganX will develop advanced analytics that integrate AlloSure, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system.

In November 2021, we acquired MedActionPlan.com LLC, or MedActionPlan, a New Jersey-based provider of medication safety, medication adherence and patient education. MedActionPlan is a leader in patient medication management for transplant patients and beyond.

In December 2021, we acquired The Transplant Pharmacy, or TTP, a transplant focused pharmacy located in Mississippi. TTP provides individualized transplant pharmacy services for patients at multiple transplant centers located throughout the U.S.

***COVID-19 Impact***

In the final weeks of March and during April 2020, with hospitals increasingly caring for COVID-19 patients, hospital administrators chose to limit or even defer, non-emergency procedures. Immunosuppressed transplant patients either self-prescribed or were asked to avoid transplant centers and caregiver visits to reduce the risk of contracting COVID-19. As a result, with transplant surveillance visits down, we experienced a slowdown in testing services volumes in the final weeks of

March and during April 2020. As a response to the COVID-19 pandemic, and to enable immune-compromised transplant patients to continue to have their blood drawn, in late March 2020, we launched RemoTraC, a remote home-based blood draw solution using mobile phlebotomy for AlloSure and AlloMap surveillance tests, as well as for other standard monitoring tests.

To date, more than 200 transplant and nephrology centers can offer RemoTraC to their patients and over 12,000 kidney, heart and lung transplant patients have enrolled. Based on existing and new relationships with partners, we have established a nationwide network of approximately 10,000 mobile phlebotomists. Following the introduction of RemoTraC and with the easing of stay-at-home restrictions and the opening up of many hospitals to non-COVID-19 patients, we have been able to maintain low levels of interruptions to our testing services volumes.

There continues to be uncertainty around the COVID-19 pandemic as the Omicron variant has caused an increase in COVID-19 cases globally, impacted the availability of medical personnel in transplant centers and the volume of transplant procedures. A sustained reduction in transplant volume can negatively impact the testing volumes, as we saw in early part of first quarter of 2022.

Our product business experienced a reduction in forecasted sales volume throughout the second and third quarters of 2020, as we were unable to undertake onsite discussions and demonstrations of our recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark authorization in May 2020. Our product business regained normalized sales volumes during the fourth quarter of 2020.

We are maintaining our testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among our employees. In areas where COVID-19 impacts healthcare operations, our field-based sales and clinical support teams are supporting providers through virtual platforms.

Although the executive orders that placed certain restrictions on operations in San Mateo County and the State of California, where our laboratory and headquarters are located, were lifted effective June 15, 2021, new orders or restrictions may be adopted in the future depending upon the COVID-19 transmission rates in our county and state, as well as other factors.

In addition, we have created a COVID-19 task force that is responsible for crisis decision making, employee communications, and enforcing all safety, monitoring and testing protocols in line with local regulations.

Due to COVID-19, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur or could impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, and there may be disruptions in our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities.

In addition, our clinical studies may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or reduced staffing due to staff members contracting COVID-19. Some patients may not be able to comply with clinical study protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to, or become infected with, COVID-19, may adversely impact our clinical trial operations.

**Financial Operations Overview**

Revenue

We derive our revenue from testing services, products sales, patient and digital solutions revenues. Revenue is recorded considering a five-step revenue recognition model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, an entity satisfies a performance obligation.

*Testing Services Revenue*

Our testing services revenue is derived from AlloSure Kidney, AlloMap Heart and AlloSure Heart tests, which represented 84% and 88% of our total revenue for the three months ended March 31, 2022 and 2021, respectively. Our testing services revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenues on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; and (v) how quickly we can successfully commercialize new product offerings.

We currently market testing services to healthcare providers through our direct sales force that targets transplant centers and their physicians, coordinators and nurse practitioners as well as general nephrologists managing transplant recipients. The healthcare providers that order the tests and on whose behalf we provide our testing services are generally not responsible for the payment of these services. Amounts received by us vary from payer to payer based on each payer's internal coverage practices and policies. We generally bill third-party payers upon delivery of a test result report to the ordering physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

*Product Revenue*

Our product revenue is derived primarily from sales of AlloSeq Tx, Olerup SSP and QTYPE products. Product revenue represented 9% of our total revenue for each of the three months ended March 31, 2022 and 2021. We recognize product revenue from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. We generally have a contract or a purchase order from a customer with the specified required terms of order, including the number of products ordered. Transaction prices are determinable and products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement. There are no further performance obligations related to a contract and revenue is recognized at the point of delivery consistent with the terms of the contract or purchase order.

*Patient and Digital Solutions Revenue*

Our patient and digital solutions revenue is mainly derived from sales of our Ottr software, XynQAPI, MedActionPlan, TTP, TransChart and Tx Access licenses, services and SaaS agreements across the digital portfolio. Patient and digital solutions revenue represented 7% and 3% of our total revenue for the three months ended March 31, 2022 and 2021, respectively.

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

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with United States Generally Accepted Accounting Principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Some of these accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. We believe that the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our financial statements. We believe the following critical accounting policies are affected by significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements:

- Revenue recognition;
- Business combinations;
- Acquired intangible assets;
- Impairment of goodwill, intangible assets and other long-lived assets;
- Stock-based compensation; and
- Common stock warrant liability.

There were no material changes in the matters for which we make critical accounting estimates in the preparation of our unaudited condensed consolidated financial statements during the three months ended March 31, 2022 as compared to those disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022.

**Recently Issued Accounting Standards**

Refer to Note 2, Summary of Significant Accounting Policies - Recent Accounting Pronouncements, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a description of recently issued accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial position and cash flows.

**Results of Operations**

***Comparison of the Three Months Ended March 31, 2022 and 2021***

***(In thousands)***

| | Three Months Ended March 31, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| Revenue: | | | |
| Testing services revenue | $ 66,444 | $ 59,281 | $ 7,163 |
| Product revenue | 6,788 | 5,778 | 1,010 |
| Patient and digital solutions revenue | 6,184 | 2,341 | 3,843 |
| Total revenue | 79,416 | 67,400 | 12,016 |
| Operating expenses: | | | |
| Cost of testing services | 17,628 | 16,483 | 1,145 |
| Cost of product | 4,399 | 3,647 | 752 |
| Cost of patient and digital solutions | 4,855 | 1,449 | 3,406 |
| Research and development | 21,880 | 16,004 | 5,876 |
| Sales and marketing | 23,148 | 15,452 | 7,696 |
| General and administrative | 26,559 | 15,223 | 11,336 |
| Total operating expenses | 98,469 | 68,258 | 30,211 |
| Loss from operations | (19,053) | (858) | (18,195) |
| Other income (expense): | | | |
| Interest income, net | 189 | 126 | 63 |
| Change in estimated fair value of common stock warrant liability | 27 | 27 | — |
| Other expense, net | (823) | (245) | (578) |
| Total other expense | (607) | (92) | (515) |
| Loss before income taxes | (19,660) | (950) | (18,710) |
| Income tax benefit | 12 | 263 | (251) |
| Net loss | $ (19,648) | $ (687) | $ (18,961) |

Testing Services Revenue

Testing services revenue increased by $7.2 million, or 12%, for the three months ended March 31, 2022 compared to the same period in 2021. The increase is primarily due to an increase of more than 8,000 AlloSure Kidney, AlloMap Heart and AlloSure Heart patient results provided in the three months ended March 31, 2022, compared to the same period in 2021.

Product Revenue

Product revenue increased by $1.0 million, or 17%, for the three months ended March 31, 2022, compared to the same period in 2021, primarily due to growth from the NGS typing products.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue increased by $3.8 million, or 164%, for the three months ended March 31, 2022 compared to the same period in 2021, primarily due to the acquisition of TTP and MedActionPlan during the fourth quarter of 2021.

Cost of Testing Services

Cost of testing services increased by $1.1 million, or 7%, for the three months ended March 31, 2022, compared to the same period in 2021. The increase is primarily due to increased testing volume, offset by stock-based compensation expense.

Cost of Product

Cost of product increased by $0.8 million, or 21%, for the three months ended March 31, 2022, compared to the same period in 2021. The increase is primarily due to increased product revenue, freight costs and consulting expenses.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions increased by $3.4 million, or 235%, for the three months ended March 31, 2022, compared to the same period in 2021. The increase is primarily due to cost of goods from the acquisition of TTP and MedActionPlan of $3.0 million, personnel related costs of $0.1 million and amortization expense of $0.1 million.

Research and Development

Research and development expenses increased by $5.9 million, or 37%, for the three months ended March 31, 2022, compared to the same period in 2021. The increase is primarily due to an increase in headcount and personnel-related costs of $2.8 million, an increase in consultants of $1.3 million, an increase in stock-based compensation expense of $0.8 million, and an increase in partnership expenses of $0.5 million.

Sales and Marketing

Sales and marketing expenses increased by $7.7 million, or 50%, for the three months ended March 31, 2022, compared to the same period in 2021. The increase is primarily due to an increase in headcount and personnel-related costs of $4.6 million, an increase in stock-based compensation expense of $1.5 million and an increase in marketing programs and travel costs of $0.8 million.

General and Administrative

General and administrative expenses increased by $11.3 million, or 74%, for the three months ended March 31, 2022, compared to the same period in 2021. The increase is primarily due to an increase in legal expenses of $6.7 million, an increase in stock-based compensation expense of $2.0 million, an increase in consultants of $1.2 million and an increase in headcount and personnel-related expenses of $0.9 million.

Other income (expense)

Other expense, net increased by $0.6 million for the three months ended March 31, 2022, compared to the same period in 2021, primarily due to the unrealized loss on the investment in Miromatrix.

***Cash Flows for the Three Months Ended March 31, 2022 and 2021***

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ (21,468) | $ (33,630) |
| Investing activities | (156,032) | 19,079 |
| Financing activities | 865 | 189,228 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | 45 | (23) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (176,590) | $ 174,654 |

Operating Activities

Net cash used in operating activities consists of net loss, adjusted for certain noncash items in the condensed consolidated statements of operations and changes in operating assets and liabilities.

Cash used in operating activities for the three months ended March 31, 2022 was $21.5 million. Our net loss of $19.6 million was our primary use of cash in operating activities that included a number of noncash items. Our noncash items included $10.6 million in stock-based compensation expense, $2.6 million of depreciation and amortization expense and $0.9 million of amortization of right-of-use assets. Net operating assets decreased $16.7 million.

Cash used in operating activities for the three months ended March 31, 2021 was $33.6 million. Our net loss of $0.7 million was our primary use of cash in operating activities that included a number of noncash items. Our noncash items included $6.5 million in stock-based compensation expense and $2.0 million of depreciation and amortization expense. Net operating assets decreased by $21.6 million, and Refund liability - CMS advance payment decreased by $20.5 million.

Investing Activities

For the three months ended March 31, 2022, net cash used in investing activities of $156.0 million was primarily related to the purchases of marketable securities of $148.5 million and $8.5 million related to additions of capital expenditures, net.

For the three months ended March 31, 2021, net cash provided by investing activities of $19.1 million was primarily related to the maturities of marketable securities of $25.1 million. These proceeds were partially offset by the acquisition of TransChart, net of cash acquired of $3.5 million, $1.2 million related to payments for acquired intangibles and $1.3 million related to additions of capital expenditures, net.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2022 of $0.9 million was primarily related to proceeds from exercises of stock options of $1.6 million and proceeds from issuances of common stock under our employee stock purchase plan of $1.0 million. These proceeds were partially offset by taxes paid related to net share settlements of restricted stock units of $1.5 million and payments of contingent consideration $0.3 million.

Net cash provided by financing activities for the three months ended March 31, 2021 of $189.2 million was primarily related to $188.7 million of proceeds from the issuance of shares of common stock in an underwritten offering, net of issuance costs, proceeds from exercises of stock options of $2.2 million and proceeds from issuances of common stock under our employee stock purchase plan of $0.7 million. These proceeds were partially offset by taxes paid related to net share settlements of restricted stock units of $2.3 million.

***Liquidity and Capital Resources***

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $402.8 million at March 31, 2022. As of March 31, 2022, we had cash, cash equivalents and marketable securities of $319.2 million and no debt outstanding.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a continued widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity.

Since March 31, 2020, and in response to the outbreak of the COVID-19 pandemic, we have increased our cash and cash equivalents. With our continuing growth, we may require additional financing in the future to fund working capital and our development of future products. Additional financing might include issuance of equity securities, including through underwritten public offerings or “at-the-market” offerings, debt offerings or financings or a combination of these financings. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. We believe our existing cash balance and expected cash from existing operations, including cash from current license agreements and future license and collaboration agreements, or a combination of these, will be sufficient to meet our anticipated cash requirements for the next 12 months.

*CMS Accelerated and Advance Payment Program for Medicare Providers*

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. Pursuant to the CARES Act, the Centers for Medicare & Medicaid Services, or CMS, expanded its Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS was authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submitted a request to the appropriate Medicare Administrative Contractor and met the required qualifications. During April 2020, we received an advance payment from CMS of approximately $20.5 million and recorded the payment as Deferred revenue - CMS advance payment on our condensed consolidated balance sheet. During December 2020, we reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021.

*CARES Act Provider Relief Fund for Medicare Providers*

Pursuant to the CARES Act, the U.S. Department of Health & Human Services, or HHS, distributed an initial tranche of $30.0 billion in funds to healthcare providers that received Medicare fee-for-service, or FFS, reimbursements in 2019. These payments to healthcare providers are not loans and will not be required to be repaid. As a condition to receiving these payments, providers must agree to certain terms and conditions and submit sufficient documentation demonstrating that the funds are being used for healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic. Due to the recent enactment of legislation and absence of definitive guidance, there is a high degree of uncertainty around the CARES Act’s implementation and we continue to assess the impact on our business. Furthermore, HHS has indicated that it, along with the Office of Inspector General, will be closely monitoring and auditing providers to ensure that recipients comply with the terms and conditions of relief programs and to prevent fraud and abuse. All providers will be subject to civil and criminal penalties for any deliberate omissions, misrepresentations or falsifications of any information given to HHS. Providers will be distributed a portion of the initial $30.0 billion based on their share of total Medicare FFS reimbursements made by the U.S. in 2019. During

April 2020, we received a payment of approximately $4.8 million, representing our portion of the initial tranche of funds recorded in other income (expense), net on the condensed consolidated statements of operations.

We are complying with the key terms and provisions of the CARES Act Provider Relief Fund which includes, among other things, the requirement that we maintain appropriate records and cost documentation. During the quarter ended September 30, 2021, we were notified by HHS that the Provider Relief Fund Reporting Portal was open for reporting on the use of Provider Relief Fund payments, and we completed and submitted a report indicating our use of the funds we received pursuant to the CARES Act.

*January 2021 Underwritten Public Offering of Common Stock*

On January 25, 2021, we sold 1,923,077 shares of our common stock through an underwritten public offering at a public offering price of $91.00 per share. The net proceeds to us from the offering were approximately $164.0 million, after deducting underwriting discounts and commissions and offering expenses.

On February 11, 2021, we sold 288,461 shares of our common stock pursuant to the full exercise of the overallotment option granted to the underwriters in connection with the offering. The net proceeds to us from the full exercise of the underwriters' overallotment option were approximately $24.7 million.

*At-the-Market Equity Offering*

On April 14, 2022, the Company entered into a sales agreement (the “Sales Agreement”) with Jefferies, LLC as sales agent (“Jefferies”), pursuant to which the Company may offer and sell, from time to time, through Jefferies, up to $200.0 million in shares of its common stock, by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Jefferies is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold through Jefferies under the Sales Agreement. Any shares of common stock offered and sold pursuant to the Sales Agreement will be issued and sold pursuant to the Company’s Registration Statement on Form S-3ASR (File No. 333-239049), filed with the SEC on June 9, 2020, including a base prospectus dated June 9, 2020, and a prospectus supplement dated April 14, 2022.

**Factors Affecting Our Performance**

COVID-19 Pandemic

COVID-19 may impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities. Clinical trials, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or reduced staffing due to staff members contracting COVID-19. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to, or become infected with, COVID-19, may adversely impact our clinical trial operations. COVID-19 may impact availability of medical personnel and reduction in transplant procedure volumes, which in-turn, could adversely affect our testing volumes.

The Number of AlloMap Heart, AlloSure Kidney and AlloSure Heart Tests We Receive and Report

The growth of our testing services business is tied to the number of AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart patient samples we receive and patient results we report. We incur costs in connection with collecting and shipping all samples and a portion of the costs when we cannot ultimately issue a report. As a result, the number of patient samples received largely correlates directly to the number of patient results reported.

Reimbursement for AlloMap Heart

AlloMap Heart test volume and the corresponding reimbursement revenue has generally increased over time since the launch of AlloMap Heart, as the ISHLT included AlloMap in guidelines, payers adopted coverage policies and no longer consider AlloMap Heart to be experimental and investigational. The rate at which our tests are covered and reimbursed has varied, and is expected to continue to vary, by payer. Revenue growth depends on our ability to maintain Medicare and third party payer reimbursement, and to expand utilization by healthcare providers.

The Protecting Access to Medicare Act of 2014, or PAMA, included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS would report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. The final PAMA ruling was issued June 17, 2016 indicating that data for reporting for the new PAMA process would begin in 2017 and the new market based rates took effect on January 1, 2018. Effective January 1, 2018, Medicare reimburses us $3,240 for AlloMap Heart testing of Medicare beneficiaries, an increase from the 2017 reimbursement rate of $2,841. The CARES Act freezes current (2020) CMS CLFS rates through 2021. Further, the CARES Act delays the reporting cycle under PAMA to January 1 and March 31, 2022. The next data collection period will become January 1 through June 30, 2024.

AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

Reimbursement for AlloSure Kidney

On September 26, 2017, we received notice that the MolDX Program developed by Palmetto GBA had set AlloSure Kidney reimbursement at $2,841. Effective October 9, 2017, AlloSure Kidney was made available for commercial testing with Medicare coverage and reimbursement. We believe the use of AlloSure Kidney, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a kidney transplant. In particular, we believe AlloSure Kidney can improve patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

Reimbursement for AlloSure Heart

In October 2020, we received a final Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, our Medicare Administrative Contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently $2,753.

Continued Growth of Product Sales

We develop, manufacture, market and sell products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and solid organs.

QTYPE enables speed and precision in HLA typing at a low to intermediate resolution for samples that require a fast turn-around-time and uses real-time PCR methodology. QTYPE received CE mark certification on April 10, 2018. Olerup SSP is used to type HLA alleles based on the SSP technology.

On May 4, 2018, we entered into a license and collaboration agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS product line for use in transplantation diagnostic testing. As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line. TruSight HLA is a high-resolution solution that uses NGS methodology. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines for use in the field of bone marrow and solid organ transplantation diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients.

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, which received CE mark authorization on January 20, 2020. Our ability to increase the clinical uptake for AlloSeq cfDNA will be a result of multiple factors, including local clinical education, customer lab technical proficiency and levels of country-specific reimbursement.

Also in September 2019, we commercially launched AlloSeq Tx, the first of its kind NGS high-resolution HLA typing solution utilizing hybrid capture technology. This technology enables the most comprehensive sequencing, covering more of the HLA genes than current solutions and adding coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx has a simple NGS workflow that reduces complexity and can reduce errors. AlloSeq Tx 17 received CE mark authorization on May 15, 2020.

In June 2020, we commercially launched AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients. This technology has the potential to provide better sensitivity and data analysis compared to current solutions on the market.

Continued Growth of Patient and Digital Sales

The growth of our patient and digital revenues is tied to the continued successful implementation of our Ottr, MedActionPlan and XynQAPI software businesses, as well as continued support and maintenance of existing MedActionPlan, Ottr, Inc. and XynManagement customers. The Ottr software, TransChart, Tx Access and XynQAPI are currently implemented in multiple locations in the U.S. The Ottr software implementation and XynQAPI implementation and support teams are based in Omaha, Nebraska. In addition, patient solutions offered by TTP in Flowood, Mississippi include hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services.

Development of Additional Services and Products

Our development pipeline includes other transplant diagnostic solutions to help clinicians and transplant centers make personalized treatment decisions throughout a transplant patient's lifetime. We expect to invest in research and development in order to develop additional products. Our success in developing new products and services will be important in our efforts to grow our business by expanding the potential market for our services and products and diversifying our sources of revenue.

Timing of Research and Development Expenses

Our spending on research and development may vary substantially from quarter to quarter. We conduct clinical studies to validate our new products, as well as on-going clinical and outcome studies to further the published evidence to support our commercialized tests. Spending on research and development for both experiments and studies may vary significantly by quarter depending on the timing of these various expenses.

**Contractual Obligations**

For a discussion regarding our significant contractual obligations as of March 31, 2022 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, please refer to Note 9 of the condensed consolidated financial statements, and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources", respectively, included elsewhere in this Quarterly Report on Form 10-Q.

**Foreign Operations**

The accompanying unaudited condensed consolidated balance sheets contain certain recorded assets in foreign countries, namely Stockholm, Sweden and Fremantle, Australia. Although these countries are considered economically stable and we

have experienced no notable burden from foreign exchange transactions, export duties or government regulations, unanticipated events in foreign countries could have a material adverse effect on our operations.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. We had cash, cash equivalents and marketable securities of $319.2 million at March 31, 2022, which consisted of bank deposits, money market funds and corporate debt securities, and we had cash and cash equivalents of $348.5 million at December 31, 2021, which consisted of bank deposits and money market funds. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of $3.2 million on our condensed consolidated financial statements.

Foreign Currency Exchange Risk

We have operations in Sweden and Australia and sell to other countries throughout the world. As a result, we are subject to significant foreign currency risks, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing services revenue is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in U.S. dollars and the Euro. Consequently, our revenue denominated in foreign currency is subject to foreign currency exchange risk. A portion of our operating expenses are incurred outside of the U.S. and are denominated in Swedish Krona, the Euro, and the Australian Dollar, which are also subject to fluctuations due to changes in foreign currency exchange rates. An unfavorable 10% change in foreign currency exchange rates for our assets and liabilities denominated in foreign currencies at March 31, 2022, would have negatively impacted our financial results for the three months ended March 31, 2022 by $0.4 million and our product revenue by $0.3 million. Currently, we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility. We will continue to reassess our approach to managing our risk relating to fluctuations in foreign currency exchange rates.

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as such terms are defined in Rules 13a-15(b) and 15d-15(e) promulgated under the Exchange Act, as of March 31, 2022. 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. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on such evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2022, our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Exchange Act, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended March 31, 2022 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

The information set forth in Note 9, *Commitments and Contingencies*, under the caption “Litigation and Indemnification Obligations” and in Note 15, *Subsequent Events*, under the caption "Olymbios Matter", to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q is incorporated herein by reference.

### ITEM 1A. RISK FACTORS

Our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission or the SEC, on February 24, 2022, or the Form 10-K, Part I –Item 1A, Risk Factors, describes important risk factors that could cause our business, financial condition, results of operations and growth prospects to differ materially from those indicated or suggested by forward-looking statements made in this Quarterly Report on Form 10-Q or presented elsewhere by management from time to time. There have been no material changes in the risk factors that appear in Part I - Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022, other than those listed below. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business.

**Risks Related to Our Business**

***We have a history of losses, and we expect to incur net losses for the next several years.***

We have incurred substantial net losses since our inception, and we may continue to incur additional losses for the next several years. For the quarter ended March 31, 2022, our net loss was $19.6 million. As of March 31, 2022, we had an accumulated deficit of $402.8 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new testing services, products and patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of KidneyCare, HeartCare, AlloSeq, AiTraC and other future solutions;
- developing, presenting and publishing additional clinical and economic utility data intended to increase payer coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- the process of fully integrating acquired companies and operations and the associated potential disruptions to our business;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize our existing and future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel;
- compliance with existing and changing laws, regulations and standards, including those relating to corporate governance and public disclosure and regulations implemented by the Securities and Exchange Commission, or the SEC, and The Nasdaq Stock Market LLC;
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a public company; and
- failure to achieve expected operating results may cause a future impairment of goodwill or other assets.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy or even continue to operate. For a detailed discussion of our financial condition and results of operations, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

***We may require additional financing.***

As of March 31, 2022, we had cash, cash equivalents and marketable securities of $319.2 million and an accumulated deficit of $402.8 million. We may require additional financing in the future to fund working capital, pay our obligations as they come due and fund our acquisitions of complementary businesses and assets. Additional financing might include issuance of equity securities, debt, cash from collaboration agreements, or a combination of these. However, there can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us.

***We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance.***

For the quarter ended March 31, 2022, revenue from Medicare for AlloMap Heart, AlloSure Kidney and AlloSure Heart represented 65% of testing services revenue. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

The Protecting Access to Medicare Act of 2014, or PAMA, included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. The final PAMA ruling was issued June 17, 2016 and the new market based rates took effect January 1, 2018. The Centers for Medicare & Medicaid Services, or CMS, uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Under PAMA, the reimbursement rate for AlloMap Heart is currently $3,240 for Medicare beneficiaries.

On September 26, 2017, we announced that the Molecular Diagnostic Services, or MolDX, Program developed by Palmetto GBA, or Palmetto, has set AlloSure Kidney reimbursement at $2,841. AlloSure Kidney began to be reimbursed for kidney transplants covered by Medicare across the United States on October 9, 2017, the effective date of the Palmetto local coverage determination, or LCD.

In October 2020, AlloSure Heart received a final Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, our Medicare Administrative contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently $2,753.

If an AlloMap Heart, AlloSure Kidney or AlloSure Heart reimbursement rate that is significantly lower than the current rate is set by CMS or MolDx in the future, it could cause us to discontinue AlloMap Heart, AlloSure Kidney or AlloSure Heart testing for Medicare patients because providing tests at a substantially lowered reimbursement rate may not be economically viable. Given the significant portion of payments represented by Medicare, our remaining test revenue may be insufficient to sustain our operations.

If future reimbursement levels are less than the current price, our revenues and our ability to achieve profitability could be impaired, and the market price of our common stock could decline. We may also not be able to maintain or increase the portion of our tests reimbursed by Medicare for a variety of other reasons, including changes in reimbursement practices and general policy shifts.

On a five-year rotational basis, Medicare requests bids for its regional Medicare Administrative Contractors, or MAC, services. The MAC for California is currently Noridian Healthcare Solutions. Our current Medicare coverage through Noridian provides for reimbursement for tests performed for qualifying Medicare patients throughout the U.S. so long as the tests are performed in our California laboratory. We cannot predict whether Noridian or any future MAC will continue to provide reimbursement for AlloMap Heart, AlloSure Kidney or AlloSure Heart at the same payment amount or with the same breadth of coverage in the future, if at all. Additional changes in the MAC processing Medicare claims for AlloSure Kidney, AlloMap Heart or AlloSure Heart could impact the coverage or payment amount for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

Any decision by CMS or its local contractors to reduce or deny coverage for our tests would have a significant adverse effect on our revenue and results of operations and ability to operate and raise capital. Any such decision could also cause affected clinicians treating Medicare covered patients to reduce or discontinue the use of our tests.

***We could become subject to legal proceedings that could be time consuming, result in costly litigation and settlements/judgments, require significant amounts of management attention and result in the diversion of significant operational resources, which could adversely affect our business, financial condition and results of operations.***

We have in the past been, and from time to time in the future may become, involved in lawsuits, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. For example, in response to our false advertising suit filed against Natera Inc., or Natera, on April 10, 2019, Natera filed a counterclaim against us on February 18, 2020 in the U.S. District Court for the District of Delaware, or the Court, alleging we made false and misleading claims about the performance capabilities of AlloSure. The suit seeks injunctive relief and unspecified monetary relief. On September 30, 2020, Natera requested leave of the Court to amend its counterclaims to include additional allegations regarding purportedly false claims we made with respect to AlloSure, and the Court granted Natera's request. The trial date commenced on March 7, 2022 and concluded on March 14, 2022, with the jury awarding the Company $44.9 million in damages, comprised of $21.2 million in compensatory damages and $23.7 million in punitive damages. The Company will not record the settlement until the post-trial motion practice has concluded.

In addition, in response to our patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against us on January 13, 2020 in the Court alleging, among other things, that AlloSure infringes Natera's U.S. Patent 10,526,658. On March 25, 2020, Natera filed an amendment to the suit alleging, among other things, that AlloSure also infringes Natera's U.S. Patent 10,597,724. The suit seeks a judgment that we have infringed Natera's patents, an order preliminarily and permanently enjoining us from any further infringement of such patents and unspecified damages. Trial is currently scheduled for July 24, 2023. We intend to defend both of these matters vigorously, and believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail.

Litigation is inherently unpredictable. It is possible that an adverse result in one or more of these possible future events could have a material adverse effect on us including increased expenses to defend, settle or resolve such litigation.

***If our laboratory facility in the U.S. becomes inoperable, we will be unable to perform AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, and future testing solutions, if any, and our business will be harmed.***

We perform all of our testing services for the U.S. in our laboratory located in Brisbane, California. We do not have redundant laboratory facilities. Brisbane, California is situated on or near earthquake fault lines. Our facility and the equipment we use to perform testing services would be costly to replace and could require substantial lead time to repair or replace if damaged or destroyed. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, power outages, wildfires, flooding, droughts and other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change and may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, we do not have earthquake insurance and thus coverage may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

In order to establish a redundant laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new clinical laboratory facility opened by us in the U.S. would be required to be certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. We would also be required to secure and maintain state licenses required by several states, including California, Florida, Maryland, New York, Rhode Island and Pennsylvania, which can take a significant amount of time and result in delays in our ability to begin operations at that facility.

If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. We also expect that it would be difficult, time-consuming and costly to train, equip and use a third-party to perform tests on our behalf. We could only use another facility with the established state licensures and CLIA certification necessary to perform AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, or future solutions following validation and other required procedures. We cannot be certain that we would be able to find another CLIA-certified facility willing or able to adopt AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart or future solutions or able to comply with the required quality and regulatory standards, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms.

Since the onset of the COVID-19 pandemic, federal, state and local governments have imposed various quarantines, shelter-in-place and similar government orders, including several orders that previously impacted operations in San Mateo County, where our laboratory and headquarters are located. These orders and others may be reinstated depending upon the COVID-19 transmission rates in our county and state, as well as other factors. If the operations in our laboratory are deemed non-essential, or if sufficient numbers of our laboratory staff are infected with COVID-19 and are unable to perform their roles, we may not be able to perform our tests for the duration of any shelter-in-place order or while we have insufficient numbers of laboratory staff, either of which could negatively impact our business, operating results and financial condition.

***Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.***

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, these investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition or results of operations, including the sustainability of our business over time. In addition, the SEC has announced proposed rules that, among other matters, will establish a framework for reporting of climate-related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.

***Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.***

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of recipient samples to our laboratory and enhanced tracking of these recipient samples. Should a carrier encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions, including those related or attributable to the COVID-19 pandemic, or related to the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, affecting delivery services we use would adversely affect our ability to receive and process recipient samples on a timely basis.

***If we are unable to raise additional capital on acceptable terms in the future, it may limit our ability to develop and commercialize new diagnostic solutions and technologies, and we may have to curtail or cease operations.***

We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- develop other solutions for clinical surveillance in transplantation;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities;
- sustain or achieve broader commercialization of AlloSure Kidney, AlloSure Lung, KidneyCare, AlloMap Heart, AlloSure Heart, HeartCare, our products and patient and digital solutions or enhancements to those tests, products and patient and digital solutions;
- acquire or license products or technologies including through acquisitions; and

- finance our capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment required to develop our new solutions;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in commercialization;
- competing technological and market developments;
- whether our diagnostic solutions become subject to additional FDA or other regulation; and
- changes in regulatory policies or laws that affect our operations.

Additional capital, if needed, may not be available on satisfactory terms, or at all. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock and would result in dilution to our stockholders. Moreover, we have the ability to sell up to $200.0 million of additional shares of our common stock to the public through an “at the market” offering pursuant to the Sales Agreement we entered into with Jefferies, LLC on April 14, 2022. Any shares of common stock issued in the at-the-market offering will result in dilution to our existing stockholders. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our solutions under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

***We rely extensively on third party service providers. Failure of these parties to perform as expected, or interruptions in our relationship with these providers or their provision of services to us, could interfere with our ability to provide test results for our testing services business and kits for our products business.***

Our relationship with any of our third party service providers may impair our ability to perform our services. The failure of any of our third party service providers to adequately perform their service obligations may reduce our revenues and increase our expenses or prevent us from providing our products and services in a timely manner if at all. In addition, our reputation, business and financial performance could be materially harmed if we are unable to, or are perceived as unable to provide test kits and perform reliable services.

We rely solely on certain suppliers to supply some of the laboratory instruments and key reagents that we use in the production of our products and/or in the performance of our tests. These sole source suppliers include Thermo Fisher, which supplies us with instruments, laboratory reagents and consumables; Roche Molecular Systems, which supplies us with laboratory reagents and consumables; Illumina, Inc., or Illumina, which supplies us with instruments, laboratory reagents, and consumables; Avantor, which supplies us with kitting services, laboratory reagents and consumables; Becton, Dickinson and Company, and Streck, which supplies us with cell preparation tubes; Beckman Coulter, which provides laboratory reagents and consumables; and Qiagen N.V., which supplies us with a proprietary buffer reagent and reagent kits. We do not have guaranteed supply agreements with Thermo Fisher, Becton, Dickinson and Company or Avantor, which exposes us to the risk that these suppliers may choose to discontinue doing business with us at any time. We periodically forecast our needs to these sole source suppliers and enter into standard purchase orders based on these forecasts.

In addition, our ABI 7900 Thermocycler, a real time PCR instrument used in AlloMap Heart, is no longer in production. Thermo Fisher has committed to provide service and support of this instrument through 2022. We believe that there are relatively few suppliers other than Thermo Fisher, Roche, Illumina, Becton, Dickinson and Company and Qiagen N.V. that are currently capable of supplying the instruments, reagents and other supplies necessary for our current products and services. Even if we were to identify secondary suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from Thermo Fisher, Becton, Dickinson and Company or Avantor, or Avantor encounters delays or difficulties in securing from Qiagen N.V., including as a result of impacts on their respective businesses due to the COVID-19 pandemic or the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, the quality and quantity of reagents, supplies or instruments that we require for our current products and services or other solutions we develop,

we may need to reconfigure our test processes, which would result in delays in commercialization or an interruption in sales. Clinicians and customers who order our current products and services rely on the continued and timely availability of our products and services. If we are unable to provide results within a timely manner, clinicians may elect not to use our products or services in the future and our business and operating results could be harmed.

***International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.***

As part of our longer-term growth strategy, we intend to target select international markets to grow our presence outside of the U.S. We currently have a commercial agreement for the promotion of AlloMap Heart in Europe with Eurobio Scientific, or Eurobio (formerly known as Diaxonhit SA). We also currently distribute products directly in Germany, UK, New Zealand, Sweden, Austria, Belgium, Netherlands and Australia and sell products via sub-distributors, in Canada and in significant markets in Europe such as France, Italy, UK and Turkey, and to certain countries in Asia, the Middle East, and Central and South America. To promote the growth of our business internationally, we will need to attract additional partners to expand into new markets.

Relying on partners for our sales and marketing subjects us to various risks, including:

- our partners may fail to commit the necessary resources to develop a market for our products, may spend the majority of their time selling products unrelated to ours, or may be unsuccessful in marketing our products for other reasons;
- under certain agreements, our partners' obligations, including their required level of promotional activities, may be conditioned upon our ability to achieve or maintain a specified level of reimbursement coverage;
- agreements with our partners may terminate prematurely due to disagreements or may result in disputes or litigation with our partners;
- we may not be able to renew existing partner agreements, or enter into new agreements, on acceptable terms;
- our existing relationships with partners may preclude us from entering into additional future arrangements;
- our partners may violate local laws or regulations, potentially causing reputational or monetary damage to our business;
- our partners may engage in sales practices that are locally acceptable but do not comply with standards required under U.S. laws that apply to us; and
- our partners may be negatively affected by the financial instability of, and austerity measures implemented by, the countries in which they operate.

If our present or future partners do not perform adequately, or we are unable to enter into agreements in new markets, we may be unable to achieve revenue growth or market acceptance in jurisdictions in which we depend on partners. In addition, conducting international operations subjects us to risks that, generally, we have not faced in the U.S., including:

- uncertain or changing regulatory registration and approval processes;
- failure by us to obtain regulatory approvals or adequate reimbursement for the use of our current and future solutions in various countries;
- competition from companies located in the countries in which we offer our products that may put us at a competitive disadvantage;
- financial risks, such as longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- logistics and regulations associated with shipping recipient samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to process solutions locally;
- difficulties in managing and staffing international operations and assuring compliance with foreign corrupt practices laws;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings;
- increased financial accounting and reporting burdens and complexities;

- multiple, conflicting and changing laws and regulations such as healthcare regulatory requirements and other governmental approvals, permits and licenses;
- the imposition of trade barriers such as tariffs, quotas, trade wars, preferential bidding or import or export licensing requirements;
- political and economic instability, including interruptions in international relations, wars, terrorism and political unrest, general security concerns, outbreak of disease, boycotts, curtailment of trade and other business restrictions, including the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia;
- fluctuations in currency exchange rates;
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, its books and records provisions or its anti-bribery provisions, as well as risks associated with other anti-bribery and anti-corruption laws; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of the above could harm our business and, consequently, our revenues and results of operations. Our expanding international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of our current and future products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. Additionally, operating internationally requires significant management attention and financial resources. We cannot be certain that the investment and additional resources required in establishing operations in other countries will produce desired levels of revenue or profitability.

In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

We are also unable to predict how changing global economic conditions or potential global health concerns such as the COVID-19 pandemic will affect our partners, suppliers and distributors. Any negative impact of such matters on our partners, suppliers or distributors may also have an adverse impact on our results of operations or financial condition.

Our success expanding internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

**Risks Related to the Healthcare Regulatory Environment**

***In order to operate our laboratory, we have to comply with the CLIA and federal state laws and regulations governing clinical laboratories and laboratory developed tests, including FDA regulations.***

We are subject to the CLIA, a federal law that regulates clinical laboratories that perform testing on specimens taken from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. If our laboratory is out of compliance with the CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as a direct plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain the CLIA compliance and certification to be eligible to bill for services provided to Medicare beneficiaries. If we were to be found to be out of compliance with the CLIA program requirements and subjected to sanction, our business could be materially harmed.

Licensure is also required for our laboratory under California law in order to conduct testing. California laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control. Moreover, several states, including New York, require that we hold licenses to test specimens from patients residing in those states. Other states have similar requirements or may adopt similar requirements in the future. In addition to our California certifications, we currently hold licenses in Florida, Maryland, New York, Pennsylvania and Rhode Island. The loss of any of these state certifications would impact our ability to provide services in those states, which could negatively affect our business.

Finally, we may be subject to regulation in foreign jurisdictions where we offer our test. Failure to maintain certification in those states or countries where it is required could prevent us from testing samples from those states or countries, could lead to the suspension or loss of licenses, certificates or authorizations, and could have an adverse effect on our business.

We were inspected as part of the customary College of American Pathologists audit and recertified in March 2022 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2024.

If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to perform AlloMap Heart, AlloSure Kidney or AlloSure Heart, which would limit our revenues and materially harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states, which could also have a material adverse effect on our business.

The FDA has traditionally chosen not to exercise its authority to regulate laboratory developed tests, or LDTs, because it believes that laboratories certified as high complexity under the CLIA, such as ours, have demonstrated expertise and ability in test procedures and analysis. However, beginning in September 2006, the FDA issued draft guidance on a subset of LDTs known as "in vitro diagnostic multivariate index assays," or IVDMIAs. According to the draft guidance, IVDMIAs do not fall within the scope of LDTs over which the FDA has exercised enforcement discretion because such tests incorporate complex and unique interpretation functions, which require clinical validation. We believed that AlloMap Heart met the definition of IVDMIA set forth in the draft guidance document. As a result, we applied for, and obtained in August 2008, 510(k) clearance for AlloMap Heart for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test.

While we believe that we are currently in material compliance with applicable laws and regulations relating to our LDTs, we cannot be certain that the FDA or other regulatory agencies would agree with our determination. A determination that we have violated these laws, or a public announcement that we are being investigated for possible violation of these laws, could hurt our business and our reputation.

**Risks Related to Our Intellectual Property**

***Our competitive position depends on maintaining intellectual property protection.***

Our ability to compete and to achieve and maintain profitability depends on our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of patents, copyrights, trademarks, trade secrets, confidentiality agreements and license agreements to protect our intellectual property rights.

Our patent position for AlloMap Heart is based on issued patents and patent applications disclosing identification of genes differentially expressed between activated and resting leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes. As of March 31, 2022, we had 24 issued U.S. patents related to transplant rejection and autoimmunity. We have four issued U.S. patents covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart. The expiration dates of these patents range from 2022 to 2024. We have eight additional patents covering additional genes or gene variants for diagnosing transplant rejection or autoimmune disease.

In connection with our June 2014 acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to one U.S. patent issued in April 2014 relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Additional patents from Stanford included in the exclusive license were issued, including one in 2017, two in 2019, and four in 2021 that further cover the use of dd-cfDNA to diagnose and predict transplant status or outcome. These patents are expiring between 2030 and 2032.

Our patents and the patents we exclusively license from others may be successfully challenged by third parties as being invalid or unenforceable. For example, in September 2021, the Court in the patent infringement case against Natera ruled that three of the patents we asserted against Natera are invalid. The Court's finding does not have any impact on our ability to continue providing AlloSure, and we have appealed the decision. However, if the Court's invalidity ruling is upheld, it may limit our ability to prevent Natera and other competitors and third parties from developing and marketing products similar to ours and we may not be able to prevent Natera and others from developing or selling products that are covered by our products or technologies, without payment to us. Third parties may independently develop similar or competing technology that avoids the patents we own or exclusively license. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

The extent to which the patent rights of life sciences companies effectively protect their products and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the proper scope of allowable claims of patents held by such companies has emerged to date in the United States. Various courts, including the United States Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostic solutions or genomic diagnostics. In the Ariosa

Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015) case, a federal court recently determined that a cfDNA product for fetal testing was not eligible for patent protection. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize a law of nature itself. What constitutes a "sufficient" additional feature for this purpose is uncertain. This evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. In particular, in September 2011, the United States Congress passed the Leahy-Smith America Invents Act, or the AIA, which became effective in March 2013. The AIA reforms United States patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. This has not yet had a material impact on the operation of our business and the protection and enforcement of our intellectual property, but it may in the future. The AIA and its implementation could still increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Patent applications in the United States and many foreign jurisdictions are not published until at least eighteen months after filing, and it is possible for a patent application filed in the United States to be maintained in secrecy until a patent is issued on the application. In addition, publications in the scientific literature often lag behind actual discoveries.

We therefore cannot be certain that others have not filed patent applications that cover inventions that are the subject of pending applications that we own or exclusively license or that we or our licensors, as applicable, were the first to invent the technology (pre-AIA) or first to file (post-AIA). Our competitors may have filed, and may in the future file, patent applications covering technology that is similar to or the same as our technology. Any such patent application may have priority over patent applications that we own or exclusively license and, if a patent issues on such patent application, we could be required to obtain a license to such patent in order to carry on our business. If another party has filed a United States patent application covering an invention that is similar to, or the same as, an invention that we own or license, we or our licensors may have to participate in an interference or other proceeding in the PTO or a court to determine priority of invention in the United States for pre-AIA applications and patents.

For post-AIA applications and patents, we or our licensors may have to participate in a derivation proceeding to resolve disputes relating to inventorship. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in our inability to obtain or retain any United States patent rights with respect to such invention.

***We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages.***

We may in the future receive offers to license patents or notices of claims of infringement, misappropriation or misuse of other parties' proprietary rights. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of outcome, is unpredictable, expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party's patent) to the party claiming infringement, develop non-infringing technology, stop selling our test or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business.

In addition, revising our current or future solutions to exclude any infringing technologies would require us to re-validate the test, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our current or future solutions. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our current or future solutions or using technology that contains the allegedly infringing intellectual property, which could harm our business. For example, see the risk factor above titled: "We could become subject to legal proceedings that could be time consuming, result in costly litigation and settlements/judgments, require significant amounts of management attention and result in the diversion of significant operational resources, which could adversely affect our business, financial condition and results of operations" for a discussion of our recently completed and ongoing litigation with Natera.

***We may be required to take further action to maintain and protect our intellectual property rights against third parties.***

In the event we determine that a party is infringing our intellectual property rights, we may try to negotiate a license arrangement with such party or we may determine to initiate a lawsuit against such party. The process of negotiating a license with a third party can be lengthy, and may take months or even years in some circumstances. In addition, it is possible that third

parties who we believe are infringing our intellectual property rights are unwilling to license our intellectual property from us on terms we can accept, or at all. For example, see the risk factor above titled: “We could become subject to legal proceedings that could be time consuming, result in costly litigation and settlements/judgments, require significant amounts of management attention and result in the diversion of significant operational resources, which could adversely affect our business, financial condition and results of operations” for a discussion of our recently completed and ongoing litigation with Natera.

The decision to commence litigation over infringement of a patent is complex and may lead to several risks to us, including the following, among others:

- the time, significant expense and distraction to management of managing such litigation;
- the uncertainty of litigation and its potential outcomes;
- the possibility that in the course of such litigation, the defendant may challenge the validity of our patents, which could result in a re-examination or post grant review of our patents and the possibility that the claims in our patents may be limited in scope or invalidated altogether;
- the potential that the defendant may successfully persuade a court that their technology or products do not infringe our intellectual property rights;
- the impact of such litigation on other licensing relationships we have or seek to establish, including the timing of renewing or entering into such relationships, as applicable, as well as the terms of such relationships;
- the potential that a defendant may assert counterclaims against us; and
- adverse publicity to us or harm to relationships we have with customers or others.

***Our business is dependent on licenses from third parties.***

We license technology from third parties necessary to develop and commercialize our products. In connection with our acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to one U.S. patent issued in April 2014 relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This technology is critical to AlloSure Kidney under the terms of the Stanford license, we are required to pay certain fees. Additional patents from Stanford included in the exclusive license were issued, including one in 2017, two in 2019, and four in 2021 that further cover the use of dd-cfDNA to diagnose and predict transplant status or outcome. These patents are expiring between 2030 and 2032.

On May 4, 2018, we entered into the License Agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina’s NGS product line for use in transplantation diagnostic testing. As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina’s TruSight HLA product line.

On April 30, 2019, we entered into the Cibiltech Agreement, pursuant to which we were granted an irrevocable, non-transferable right to commercialize Cibiltech’s proprietary software, iBox, for the predictive analysis of post-transplantation kidney allograft loss in the field of transplantation in the U.S. for a period of ten years.

In April 2020, we entered into a license agreement with Cornell University pursuant to which we were granted exclusive rights to three patents and two patent applications covering methods and technology for measurement of gene expression in urine to diagnose kidney transplant rejection.

In June 2021, we entered into a strategic agreement with OrganX to develop clinical decision support tools across the transplant patient journey. Together, we and OrganX will develop advanced analytics that integrate AlloSure, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system.

Our rights to use this and other licensed technologies, data and materials and to employ the inventions claimed in licensed patents are subject to the continuation of and our compliance with the terms of the applicable licenses.

Termination of the license could prevent us from producing or selling some or all of our products. Failure of a licensor to abide by the terms of a license or to prevent infringement by third parties could also harm our business and negatively impact our market position.

**Risks Related to Cybersecurity**

***We face four primary risks relative to protecting critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks. In addition, an application, data security or network incident may allow unauthorized access to our systems or data or our customers’ data, disable access to our service, harm our reputation, create additional liability and adversely impact our financial results.***

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store our critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. In addition, as a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology which may create additional opportunities for cybercriminals to exploit vulnerabilities. While we maintain monitoring practices and protections for our information technology to reduce these risks and test our systems on an ongoing basis for any potential threats, there can be no assurance that these efforts will prevent a cyber-attack or other security breach.

Third parties have attempted, and may in the future attempt, to fraudulently induce employees, contractors or consumers into disclosing sensitive information such as user names, passwords or other information or otherwise compromise the security of our internal networks, electronic systems and/or physical facilities in order to gain access to our data or our critical information, which could result in significant legal and financial exposure. We have experienced cybersecurity incidents and expect that we will continue to be subject to cybersecurity attacks in the future. In addition, a contractor or other third party with whom we do business, as well as parties with which we do not do business, may attempt to circumvent our security measures or obtain such information, and may purposefully or inadvertently cause a breach involving sensitive information. While we still continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third party training regarding phishing, malware, and other cyber risks, monitoring of networks and systems and maintenance of back up of protective systems), which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shut downs due to attack by hackers or breaches, phishing scams, ransomware, systems failures, computer viruses, employee errors or other malfeasance. A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks or those of our third-party billing agent, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill our payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future products and solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position. We have insurance coverage in place for certain potential liabilities and costs relating to service interruptions, data corruption, cybersecurity risks, data security incidents and/or network security breaches, but this insurance is limited in amount, subject to a deductible, and may not be adequate to cover us for all costs arising from these incidents. Furthermore, in the future such insurance may not be available on commercially reasonable terms, or at all.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. For example, the California Consumer Privacy Act, or the CCPA, took effect on January 1, 2020. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give such consumers the right to opt-out of certain sales of personal information. The CCPA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the CCPA on our business.

Internationally, the General Data Protection Regulation, or the GDPR, took effect in May 2018 within the European Economic Area, or the EEA, and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. Furthermore, other international jurisdictions, including Singapore, South Korea, China, Brazil, Mexico and Australia, have also implemented laws relating to data privacy and protection.

**Risks Related to Our Common Stock**

***Our operating results may fluctuate, which could cause our stock price to decrease.***

Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. From January 3, 2022 to March 31, 2022, our closing stock price ranged from $28.19 to $46.60 per share. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

- demand by clinicians and recipients for our current and future solutions, if any;
- coverage and reimbursement decisions by third-party payers and announcements of those decisions;
- clinical trial results and publication of results in peer-reviewed journals or the presentation at medical conferences;
- the inclusion or exclusion of our current and future solutions in large clinical trials conducted by others;
- new or less expensive tests and services or new technology introduced or offered by our competitors or us;
- the level of our development activity conducted for new solutions, and our success in commercializing these developments;
- our ability to efficiently integrate the business of new acquisitions;
- the level of our spending on test commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development;
- changes in the regulatory environment, including any announcement from the FDA regarding its decisions in regulating our activities;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel;
- public health emergencies such as the COVID-19 pandemic; and
- general market conditions.

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, national stock exchanges, and in particular the market for life science companies, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Moreover, we may be subject to additional securities class action litigation as a result of volatility in the price of our common stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

***The market price of our common stock has been and will likely continue to be volatile, and you could lose all or part of your investment.***

Our common stock is currently traded on the Nasdaq Global Market, but we can provide no assurances that there will be active trading on that market or on any other market in the future. If there is no active market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. From January 3, 2022 to March 31, 2022, our closing stock price ranged from $28.19 to $46.60 per share. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022, factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of life sciences stocks;
- changes in operating performance and stock market valuations of other life sciences companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders;

- entering into financing or other arrangements with rights or terms senior to the interests of common stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management;
- public health emergencies, including the COVID-19 pandemic; and
- general economic conditions and slow or negative growth of our markets.

**General Risk Factors**

***The impact of the Russian invasion of Ukraine on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.***

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and several European and Asian countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and customers. For example, a prolonged conflict may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the war in Ukraine may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; our ability to maintain or increase our product prices; disruptions in global supply chains; our exposure to foreign currency fluctuations; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

***Issuer Purchases of Equity Securities***

We satisfy certain U.S. federal and state tax withholding obligations due upon the vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such award a number of shares of our common stock with an aggregate fair market value on the date of vesting equal to the minimum tax withholding obligations. The following table sets forth information with respect to shares of our common stock repurchased by us to satisfy certain tax withholding

obligations during the three months ended March 31, 2022:

| | (a) Total Number of Shares (or Units) Purchased | | (b) Average Price Paid per Share (or Unit) |
|---|---|---|---|
| January 1, 2022 - January 31, 2022 | 19,606 | (1) | $ 14.49 |
| February 1, 2022 - February 28, 2022 | 11,173 | (1) | 13.82 |
| March 1, 2022 - March 31, 2022 | 4,858 | (1) | 11.86 |
| Total | 35,637 | | — |

(1) Represents shares of our common stock withheld from employees for the payment of taxes.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

| Exhibit Number | |
|---|---|
| 3.1(1) | Amended and Restated Certificate of Incorporation. |
| 3.2(2) | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of CareDx, Inc., filed June 17, 2021. |
| 3.3(3) | Amended and Restated Bylaws. |
| 4.1(4) | Form of Registrant's common stock certificate. |
| 4.2(5)# | 2014 Equity Incentive Plan, as amended. |
| 4.3(6)# | Form of Option Agreement under the 2014 Equity Incentive Plan for New Options. |
| 4.4(7)# | 2014 Employee Stock Purchase Plan and forms of agreements thereunder. |
| 4.5(8)# | 2016 Inducement Equity Incentive Plan. |
| 4.6(9) | Form of Warrant. |
| 4.7(10)# | CareDx, Inc. 2019 Inducement Equity Incentive Plan. |
| 31.1* | Certification of Periodic Report by Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Periodic Report by Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1** | Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101) |
| (1) | Incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on August 28, 2014. |
| (2) | Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on June 21, 2021. |
| (3) | Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed with the SEC on June 21, 2021. |
| (4) | Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K filed with the SEC on March 31, 2015. |
| (5) | Incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-Q filed with the SEC on July 29, 2021. |
| (6) | Incorporated by reference to Exhibit 99(d)(3) to the Registrant's Form SC TO-I filed with the SEC on October 12, 2017. |
| (7) | Incorporated by reference to Exhibit 4.5 to the Registrant's Form S-8 filed with the SEC on July 18, 2014. |
| (8) | Incorporated by reference to Exhibit 4.5 to the Registrant's Form 10-Q filed with the SEC on July 29, 2021. |
| (9) | Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on April 14, 2016. |
| (10) | Incorporated by reference to Exhibit 4.7 to the Registrant's Form 10-Q filed with the SEC on July 29, 2021. |
| # | Indicates management contract or compensatory plan or arrangement. |
| * | Filed herewith. |
| ** | Furnished herewith. |

**SIGNATURES**

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

CAREDX, INC.
(Registrant)

Date: May 5, 2022

By: /s/ REGINALD SEETO, MBBS
Reginald Seeto, MBBS
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ ANKUR DHINGRA
Ankur Dhingra
Chief Financial Officer
(Principal Accounting and Financial Officer)

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Reginald Seeto, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2022

By: /s/ Reginald Seeto, MBBS
Reginald Seeto, MBBS
Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ankur Dhingra, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2022

By: /s/ Ankur Dhingra
Ankur Dhingra
Chief Financial Officer
(Principal Accounting and Financial Officer)

**Exhibit 32.1**

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

In connection with the Quarterly Report on Form 10-Q of CareDx, Inc. (the "Company") for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

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

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

By: /s/ Reginald Seeto, MBBS
Reginald Seeto, MBBS
President and Chief Executive Officer
*(Principal Executive Officer)*
Date: May 5, 2022

By: /s/ Ankur Dhingra
Ankur Dhingra
Chief Financial Officer
*(Principal Accounting and Financial Officer)*
Date: May 5, 2022

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.