

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **February 24, 2022**

ICU MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-34634 (Commission File Number)	33-0022692 (IRS Employer Identification No.)
951 Calle Amanecer , San Clemente , California (Address of principal executive offices)		92673 (Zip Code)

(949) 366-2183

Registrant's telephone number, including area code

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 \$0.10 per share	ICUI	<u>The Nasdaq Stock Market LLC</u> (Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition

ICU Medical, Inc. announced its earnings for the fourth quarter of 2021.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release, dated February 24, 2022 announcing ICU Medical, Inc.'s fourth quarter 2021 earnings.

104 Cover Page Interactive Data File (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)

SIGNATURE

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 hereunto duly authorized.

ICU MEDICAL, INC.

Date: February 24, 2022

By: /s/ Brian M. Bonnell
Brian M. Bonnell
Chief Financial Officer and Treasurer

**ICU Medical Announces Fourth Quarter 2021 Results
and Provides Fiscal Year 2022 Guidance**

SAN CLEMENTE, Calif., February 24, 2022 (GLOBE NEWSWIRE) -- ICU Medical, Inc. (Nasdaq:ICUI), a leader in the development, manufacture and sale of innovative medical products, today announced financial results for the quarter ended December 31, 2021.

Fourth Quarter 2021 Results

Fourth quarter 2021 revenue was \$340.5 million, compared to \$320.5 million in the same period last year. GAAP gross profit for the fourth quarter of 2021 was \$127.5 million, as compared to \$119.9 million in the same period last year. GAAP gross margin for the fourth quarter of 2021 was 37%, as compared to 37% in the same period last year. GAAP net income for the fourth quarter of 2021 was \$19.9 million, or \$0.91 per diluted share, as compared to GAAP net income of \$26.1 million, or \$1.21 per diluted share, for the fourth quarter of 2020. Adjusted diluted earnings per share for the fourth quarter of 2021 was \$1.82 as compared to \$1.77 for the fourth quarter of 2020. Also, adjusted EBITDA was \$64.2 million for the fourth quarter of 2021 as compared to \$59.8 million for the fourth quarter of 2020.

Adjusted EBITDA and adjusted diluted earnings per share are measures calculated and presented on the basis of methodologies other than in accordance with GAAP. Please refer to the Use of Non-GAAP Financial Information following the financial statements herein for further discussion and reconciliations of these measures to GAAP measures.

Vivek Jain, ICU Medical's Chief Executive Officer, said, "Fourth quarter results were generally in line with our expectations."

Revenues by product line for the three and twelve months ended December 31, 2021 and 2020 were as follows (in millions):

Product Line	Three months ended December 31,			Twelve months ended December 31,		
	2021	2020	\$ Change	2021	2020	\$ Change
Infusion Consumables	\$ 147.8	\$ 123.1	\$ 24.7	\$ 555.2	\$ 473.7	\$ 81.5
Infusion Systems	92.6	91.8	0.8	352.3	359.7	(7.4)
IV Solutions*	87.6	93.6	(6.0)	359.5	389.0	(29.5)
Critical Care	12.5	12.0	0.5	49.3	48.6	0.7
	<u>\$ 340.5</u>	<u>\$ 320.5</u>	<u>\$ 20.0</u>	<u>\$ 1,316.3</u>	<u>\$ 1,271.0</u>	<u>\$ 45.3</u>

*IV Solutions includes \$10.6 million and \$42.8 million of contract manufacturing to Pfizer for the three and twelve months ended December 31, 2021, respectively, as compared to \$11.3 million and \$56.1 million for the same periods in the prior year.

Fiscal Year 2022 Guidance

For the Fiscal Year 2022, the Company expects adjusted EBITDA to be in the range of \$450 million to \$500 million, and adjusted diluted EPS to be in the range of \$9.00 to \$10.50.

Conference Call

The Company will host a conference call to discuss its fourth quarter 2021 financial results, today at 4:30 p.m. ET (1:30 p.m. PT). The call can be accessed at (855) 327-6837, international (408) 774-4587, conference ID 10017891. The conference call will be simultaneously available by webcast, which can be accessed by going to the Company's website at www.icumed.com, clicking on the Investors tab, clicking on Event Calendar and clicking on the Webcast icon and following the prompts. The webcast will also be available by replay.

About ICU Medical

ICU Medical (Nasdaq:ICUI) is a global leader in infusion systems, infusion consumables and high-value critical care products used in hospital, alternate site and home care settings. Our team is focused on providing quality, innovation and value to our clinical customers worldwide. ICU Medical is headquartered in San Clemente, California. More information about ICU Medical can be found at www.icumed.com.

Forward Looking Statements

This press release 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. Such statements contain words such as "will," "expect," "believe," "could," "would," "estimate," "continue," "build," "expand" or the negative thereof or comparable terminology, and may include (without limitation) information regarding the Company's expectations, goals or intentions regarding the future, including our full year 2022 guidance. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about the Company and assumptions management believes are reasonable, all of which are subject to risks and uncertainties that could cause actual results and events to differ materially from those stated in the forward-looking statements. These risks and uncertainties include, but are not limited to, decreased demand for the Company's products, decreased free cash flow, the inability to recapture conversion delays or part/resource shortages on anticipated timing, or at all, changes in product mix, increased competition from competitors, lack of growth or improving efficiencies, unexpected changes in the Company's arrangements with its largest customers, the impact of the ongoing COVID-19 pandemic on the Company and our financial results and the Company's ability to meet expectations regarding integration of the Smiths Medical 2020 Limited business. Future results are subject to risks and uncertainties, including the risk factors, and other risks and uncertainties, described in the Company's filings with the Securities and Exchange Commission, which include those in the Company's most recent Annual Report on Form 10-K and our subsequent filings. Forward-looking statements contained in this press release are made only as of the date hereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31, 2021	December 31, 2020
	(Unaudited)	(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 552,827	\$ 396,097
Short-term investment securities	14,420	14,687
TOTAL CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENT SECURITIES	567,247	410,784
Accounts receivable, net of allowance for doubtful accounts	105,894	124,093
Inventories	290,235	314,928
Prepaid income taxes	19,586	29,480
Prepaid expenses and other current assets	46,847	41,492
TOTAL CURRENT ASSETS	1,029,809	920,777
PROPERTY, PLANT AND EQUIPMENT, net	468,365	466,628
OPERATING LEASE RIGHT-OF-USE ASSETS	39,847	46,571
LONG-TERM INVESTMENT SECURITIES	4,620	12,974
GOODWILL	43,439	33,001
INTANGIBLE ASSETS, net	188,311	197,231
DEFERRED INCOME TAXES	42,604	31,034
OTHER ASSETS	63,743	55,475
TOTAL ASSETS	\$ 1,880,738	\$ 1,763,691
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 81,128	\$ 71,864
Accrued liabilities	118,195	97,021
Income tax payable	1,454	303
Contingent earn-out liability	—	26,300
TOTAL CURRENT LIABILITIES	200,777	195,488
CONTINGENT EARN-OUT LIABILITY	2,589	—
OTHER LONG-TERM LIABILITIES	41,830	47,835
DEFERRED INCOME TAXES	1,490	1,663
INCOME TAX LIABILITY	18,021	16,440
COMMITMENTS AND CONTINGENCIES	—	—
STOCKHOLDERS' EQUITY:		
Convertible preferred stock, \$1.00 par value; Authorized — 500 shares; Issued and outstanding — none	—	—
Common stock, \$0.10 par value; Authorized — 80,000 shares; Issued — 21,280 and 21,058 shares at December 31, 2021 and 2020, respectively, and outstanding — 21,280 and 21,058 shares at December 31, 2021 and 2020, respectively	2,128	2,106
Additional paid-in capital	721,412	693,068
Treasury stock, at cost	(27)	(39)
Retained earnings	911,787	808,652
Accumulated other comprehensive loss	(19,269)	(1,522)
TOTAL STOCKHOLDERS' EQUITY	1,616,031	1,502,265
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,880,738	\$ 1,763,691

⁽¹⁾ December 31, 2020 balances were derived from audited consolidated financial statements.

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2021	2020	2021	2020
TOTAL REVENUES	\$ 340,525	\$ 320,451	\$ 1,316,308	\$ 1,271,004
COST OF GOODS SOLD	213,035	200,577	824,818	809,507
GROSS PROFIT	127,490	119,874	491,490	461,497
OPERATING EXPENSES:				
Selling, general and administrative	81,456	73,552	302,583	283,953
Research and development	13,166	11,797	47,498	42,948
Restructuring, strategic transaction and integration	9,043	5,506	18,037	28,409
Change in fair value of contingent earn-out	—	2,000	—	9,000
Contract settlement	—	—	127	(975)
TOTAL OPERATING EXPENSES	103,665	92,855	368,245	363,335
INCOME FROM OPERATIONS	23,825	27,019	123,245	98,162
INTEREST EXPENSE	(366)	(170)	(858)	(1,753)
OTHER (EXPENSE) INCOME, net	(122)	3,260	799	1,085
INCOME BEFORE INCOME TAXES	23,337	30,109	123,186	97,494
PROVISION FOR INCOME TAXES	(3,412)	(3,967)	(20,051)	(10,624)
NET INCOME	\$ 19,925	\$ 26,142	\$ 103,135	\$ 86,870
NET INCOME PER SHARE				
Basic	\$ 0.94	\$ 1.24	\$ 4.86	\$ 4.16
Diluted	\$ 0.91	\$ 1.21	\$ 4.74	\$ 4.02
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	21,257	21,016	21,206	20,907
Diluted	21,807	21,614	21,781	21,591

Use of Non-GAAP Financial Information

This press release contains financial measures that are not calculated in accordance with U.S. generally accepted accounting principles ("GAAP"). The non-GAAP financial measures should be considered supplemental to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. There are material limitations in using these non-GAAP financial measures because they are not prepared in accordance with GAAP and may not be comparable to similarly titled non-GAAP financial measures used by other companies, including peer companies. Our management believes that the non-GAAP data provides useful supplemental information to management and investors regarding our performance and facilitates a more meaningful comparison of results of operations between current and prior periods. We use non-GAAP financial measures in addition to and in conjunction with GAAP financial measures to analyze and assess the overall performance of our business, in making financial, operating and planning decisions, and in determining executive incentive compensation. The non-GAAP financial measures included in this press release are adjusted EBITDA and adjusted diluted earnings per share ("Adjusted Diluted EPS").

Adjusted EBITDA excludes the following items from net income:

Interest, net: We exclude interest in deriving adjusted EBITDA as interest can vary significantly among companies depending on a company's level of income generating instruments and/or level of debt.

Stock compensation expense: Stock-based compensation is generally fixed at the time the stock-based instrument is granted and amortized over a period of several years. The value of stock options is determined using a complex formula that incorporates factors, such as market volatility, that are beyond our control. The value of our restricted stock awards is determined using the grant date stock price, which may not be indicative of our operational performance over the expense period. Additionally, in order to establish the fair value of performance-based stock awards, which are currently an element of our ongoing stock-based compensation, we are required to apply judgment to estimate the probability of the extent to which performance objectives will be achieved. Based on the above factors, we believe it is useful to exclude stock-based compensation in order to better understand our operating performance.

Intangible asset amortization expense: We do not acquire businesses or capitalize certain patent costs on a predictable cycle. The amount of purchase price allocated to intangible assets and the term of amortization can vary significantly and are unique to each acquisition. Capitalized patent costs can vary significantly based on our current level of development activities. We believe that excluding amortization of intangible assets provides the users of our financial statements with a consistent basis for comparison across accounting periods.

Depreciation expense: We exclude depreciation expense in deriving adjusted EBITDA because companies utilize productive assets of different ages and the depreciable lives can vary significantly resulting in considerable variability in depreciation expense among companies.

Restructuring, strategic transaction and integration: We incur restructuring and strategic transaction charges that result from events, which arise from unforeseen circumstances and/or often occur outside of the ordinary course of our ongoing business. Although these events are reflected in our GAAP financial statements, these unique transactions may limit the comparability of our ongoing operations with prior and future periods.

Quality and regulatory initiatives and remediation: We incur charges to develop processes and systems to comply with certain quality standards and regulations as well as to remediate issues related to our quality systems and manufacturing operations as a result of regulatory inspections. We also incur charges related to field corrective actions for specific products which may be related to recalls initiated by the company or required by regulatory authorities. We exclude items that are either non-cash or not normal, recurring operating expenses due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing. In 2022, this will include costs related to remediation initiatives related to the FDA Warning Letter received by Smiths Medical 2020 Limited in 2021.

Change in fair value of contingent earn-out: We exclude the impact of certain amounts recorded in connection with business combinations. We exclude items that are either non-cash or not normal, recurring operating expenses due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing.

Adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair market value: The inventory step-up represents the expense recognition of fair value adjustments in excess of the historical cost basis of inventory obtained through acquisition, these charges are outside of our normal operations and are excluded.

Disposition of certain assets: Occasionally, we may dispose of certain assets if no longer needed for current operations. We exclude any gains or losses recognized on the sale of these assets in determining our non-GAAP financial measures as they may limit the comparability of our ongoing operations with prior and future periods and distort the evaluation of our normal operating performance.

Taxes: We exclude taxes in deriving adjusted EBITDA as taxes are deemed to be non-core to the business and may limit the comparability of our ongoing operations with prior and future periods and distort the evaluation of our normal operating performance.

Adjusted Diluted EPS excludes from diluted EPS, net of tax, stock compensation expense, intangible asset amortization expense, restructuring, strategic transaction and integration, change in fair value of contingent earn-out, adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair value and disposition of certain assets. The tax effect on the above adjustments is calculated using the specific tax rate applied to each adjustment based on the nature of the item/or the tax jurisdiction in which the item has been recorded.

From time to time in the future, there may be other items that we may exclude if we believe that doing so is consistent with the goal of providing useful information to investors and management.

The following tables reconcile our GAAP and non-GAAP financial measures:

ICU MEDICAL, INC. AND SUBSIDIARIES
Reconciliation of GAAP to Non-GAAP Financial Measures (Unaudited)
(In thousands, except per share data)

	Adjusted EBITDA	
	Three months ended December 31,	
	2021	2020
GAAP net income	\$ 19,925	\$ 26,142
Non-GAAP adjustments:		
Interest, net	(366)	(519)
Stock compensation expense	8,105	5,340
Depreciation and amortization expense	23,133	21,594
Restructuring, strategic transaction and integration	9,043	5,506
Change in fair value of contingent earn-out	—	2,000
Adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair value	912	—
Disposition of certain assets	—	(4,237)
Provision for income taxes	3,412	3,967
Total non-GAAP adjustments	44,239	33,651
Adjusted EBITDA	\$ 64,164	\$ 59,793

	Adjusted diluted earnings per share	
	Three months ended December 31,	
	2021	2020
GAAP diluted earnings per share	\$ 0.91	\$ 1.21
Non-GAAP adjustments:		
Stock compensation expense	0.37	0.25
Amortization expense	0.29	0.27
Restructuring, strategic transaction and integration	0.41	0.25
Change in fair value of contingent earn-out	—	0.09
Adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair value	0.04	—
Disposition of certain assets	—	(0.20)
Estimated income tax impact from adjustments	(0.20)	(0.10)
Adjusted diluted earnings per share	\$ 1.82	\$ 1.77

ICU MEDICAL, INC. AND SUBSIDIARIES

Reconciliation of GAAP to Non-GAAP Financial Measures - Fiscal Year 2022 Outlook* (Unaudited)

(In millions, except per share data)

	<u>Low End of Guidance</u>	<u>High End of Guidance</u>
GAAP net income	\$ 50	\$ 89
Non-GAAP adjustments:		
Interest, net	59	59
Stock compensation expense	35	35
Depreciation and amortization expense	143	143
Restructuring, strategic transaction and integration	80	80
Quality and regulatory initiatives and remediation	69	69
Change in fair value of contingent earn-out	—	—
Provision for income taxes	14	25
Total non-GAAP adjustments	\$ 400	\$ 411
Adjusted EBITDA	\$ 450	\$ 500
GAAP diluted earnings per share	\$ 2.05	\$ 3.65
Non-GAAP adjustments:		
Stock compensation expense	1.43	1.43
Amortization expense	1.43	1.43
Restructuring, strategic transaction and integration	3.28	3.28
Quality and regulatory initiatives and remediation	2.83	2.83
Change in fair value of contingent earn-out	—	—
Estimated income tax impact from adjustments	(2.02)	(2.12)
Adjusted diluted earnings per share	\$ 9.00	\$ 10.50

*The company's Fiscal Year 2022 outlook includes the impact of items that are known and can be reasonably estimated as of the date of the release. As such, the company's outlook does not reflect the impact of the pending purchase price allocation for the Smiths Medical 2020 Limited acquisition, which will result in certain adjustments, including but not limited to, the reversal of the cost recognition related to the purchase accounting write-up of inventory to fair market value, amortization expense on acquired intangible assets, additional depreciation expense related to the fair market value adjustment for acquired property plant and equipment and the potential change in fair value of contingent earn-out.

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