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) November 8, 2018

ICU MEDICAL, INC.

(Exact name of registrant as specified in its charter)

DELAWARE 001-34634 33-0022692

(State or other jurisdiction (IRS Employer (Commission File Number) Identification No.)

951 Calle Amanecer, San Clemente, California

92673

(Address of principal executive offices)

(Zip Code)

(949) 366-2183

Registrant's telephone number, including area code $$\mathrm{N}/\mathrm{A}$$

(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):

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

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 o

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. o

Item 2.02. Results of Operations and Financial Condition

ICU Medical, Inc. announced its earnings for the third quarter of 2018.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

99.1 Press release, dated November 8, 2018 announcing ICU Medical, Inc.'s third quarter 2018 earnings.

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: November 8, 2018 By: /s/ Scott E. Lamb

Scott E. Lamb

Chief Financial Officer and Treasurer

ICU Medical, Inc. Announces Third Quarter 2018 Results

Company Modifies FY 2018 Guidance and Provides Initial FY 2019 Adjusted EBITDA Guidance

SAN CLEMENTE, Calif., November 8, 2018 (GLOBE NEWSWIRE) -- ICU Medical, Inc. (Nasdaq:ICUI), a leader in the development, manufacture and sale of innovative medical products used in infusion therapy and critical care applications, today announced financial results for the quarter ended September 30, 2018.

Third Quarter 2018 Results

Third quarter 2018 revenue was \$327.2 million, compared to \$343.2 million in the same period last year. GAAP gross profit for the third quarter of 2018 was \$134.6 million, as compared to \$111.6 million in the same period last year. GAAP gross margin for the third quarter of 2018 was 41%, as compared to 33% in the same period last year. GAAP net income for the third quarter of 2018 was \$0.2 million, or \$0.01 per diluted share, as compared to GAAP net income of \$0.1 million, or \$0.01 per diluted share, for the third quarter of 2017. Adjusted diluted earnings per share for the third quarter of 2018 were \$1.85 as compared to \$1.12 for the third quarter of 2017. Also, adjusted EBITDA was \$68.4 million for the third quarter of 2018 as compared to \$55.4 million for the third quarter of 2017.

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, "Third quarter revenues for Infusion Consumables and Infusion Systems were in line with our expectations and IV Solutions was below our expectations. Adjusted EBITDA and adjusted diluted earnings per share were slightly above our expectations."

Revenues by product line for the three and nine months ended September 30, 2018 and 2017 were as follows (in millions):

	Three mo Septen	 		Nine months ended September 30,							
Product Line	2018	2017	\$ Change	% Change		2018		2017	C	\$ Change	% Change
Infusion Consumables	\$ 117.8	\$ 92.7	\$ 25.1	27.1 %	\$	361.5	\$	245.9		115.6	47.0 %
IV Solutions	114.4	143.7	(29.3)	(20.4)%		394.2		375.5		18.7	5.0 %
Infusion Systems	81.5	82.8	(1.3)	(1.6)%		263.3		202.6		60.7	30.0 %
Critical Care	13.5	12.9	0.6	4.7 %		40.7		37.2		3.5	9.4 %
Other	_	11.1	(11.1)	(100.0)%		_		61.3		(61.3)	(100.0)%
	\$ 327.2	\$ 343.2	\$ (16.0)	(4.7)%	\$	1,059.7	\$	922.5	\$	137.2	14.9 %

The Company ended the third quarter of 2018 with a strong balance sheet. During the third quarter of 2018, cash, cash equivalents and short and long-term investment securities increased by \$25.6 million to \$358.7 million at September 30, 2018 and working capital was \$710.8 million.

Fiscal Year 2018 Guidance Update and Initial Fiscal 2019 Guidance

The Company is modifying its full year 2018 guidance of adjusted EBITDA from a range of \$270 million to \$280 million to a range of \$280 million to \$290 million and adjusted earnings per share from a range of \$8.30 to \$8.70 to a range of \$8.45 to \$8.85. The Company is also providing initial 2019 adjusted EBITDA guidance in the range of \$315 million to \$340 million.

Conference Call

The Company will host a conference call to discuss third quarter 2018 financial results today at 4:30 p.m. EDT (1:30 p.m. PDT). The call can be accessed at (800) 936-9761, international (408) 774-4587, conference ID 7968668. 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 the Webcast icon and following the prompts. The webcast will also be available by replay.

About ICU Medical, Inc.

ICU Medical, Inc. (Nasdaq:ICUI) develops, manufactures and sells innovative medical products used in infusion therapy and critical care applications. ICU Medical's product portfolio includes IV smart pumps, sets, connectors, closed system transfer devices for hazardous drugs, sterile IV solutions, cardiac monitoring systems, along with pain management and safety software technology designed to help meet clinical, safety and workflow goals. ICU Medical is headquartered in San Clemente, California. More information about ICU Medical, Inc. 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. 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 continued growth or improving efficiencies, unexpected changes in the Company's arrangements with its largest customers and the Company's ability to meet expectations regarding the integration of the Hospira infusion systems 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 Annual Report on Form 10-K for the year ended December 31, 2017 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)

	Se	eptember 30, 2018	December 31, 2017
		(Unaudited)	 (1)
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$	318,816	\$ 290,072
Short-term investment securities		36,960	10,061
TOTAL CASH, CASH EQUIVALENTS AND INVESTMENT SECURITIES		355,776	 300,133
Accounts receivable, net of allowance for doubtful accounts of \$5,088 at September 30, 2018 and \$3,311 at December 31, 2017		144,535	112,696
Inventories		291,840	288,657
Prepaid income taxes		24,447	10,594
Prepaid expenses and other current assets		26,306	41,286
Related-party receivable		70,408	98,807
Assets held-for-sale		_	 12,489
TOTAL CURRENT ASSETS		913,312	864,662
PROPERTY AND EQUIPMENT, net		424,897	398,684
LONG-TERM INVESTMENT SECURITIES		2,922	14,579
GOODWILL		13,199	12,357
INTANGIBLE ASSETS, net		131,811	143,753
DEFERRED INCOME TAXES		20,341	24,775
OTHER ASSETS		38,693	 38,141
TOTAL ASSETS	\$	1,545,175	\$ 1,496,951
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Accounts payable	\$	70,566	\$ 78,228
Accrued liabilities		131,954	132,064
TOTAL CURRENT LIABILITIES		202,520	210,292
CONTINGENT EARN-OUT LIABILITY		47,500	27,000
OTHER LONG-TERM LIABILITIES		29,057	55,326
DEFERRED INCOME TAXES		1,193	1,487
INCOME TAX LIABILITY		4,592	4,592
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 and outstanding, 20,489 shares at September 30, 2018 and 20,210 shares at December 31, 2017		2,049	2,021
Additional paid-in capital		651,752	625,568
Treasury stock, at cost		(128)	_
Retained earnings		628,101	585,624
Accumulated other comprehensive loss		(21,461)	 (14,959)
TOTAL STOCKHOLDERS' EQUITY		1,260,313	1,198,254
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	1,545,175	\$ 1,496,951

 $[\]overline{\ ^{(1)}}$ December 31, 2017 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 September 30,			nths ended nber 30,		
	' <u></u>	2018		2017	2018		2017
REVENUES:							
Net sales	\$	327,169	\$	343,084	\$ 1,059,662	\$	921,544
Other		_		152	_		945
TOTAL REVENUE		327,169		343,236	1,059,662		922,489
COST OF GOODS SOLD		192,582		231,638	624,274		633,884
GROSS PROFIT		134,587		111,598	435,388		288,605
OPERATING EXPENSES:							
Selling, general and administrative		78,068		76,820	248,603		226,812
Research and development		13,181		12,769	39,342		37,377
Restructuring, strategic transaction and integration		24,012		18,711	64,271		68,033
Change in fair value of contingent earn-out		18,500		7,000	20,500		13,000
Contract settlement		_		_	28,917		_
TOTAL OPERATING EXPENSES		133,761		115,300	 401,633		345,222
INCOME (LOSS) FROM OPERATIONS		826		(3,702)	33,755		(56,617)
BARGAIN PURCHASE GAIN		_		8,534	_		71,771
INTEREST EXPENSE		(283)		(705)	(548)		(1,743)
OTHER INCOME (EXPENSE), net		894		583	1,650		(2,030)
INCOME BEFORE INCOME TAXES		1,437		4,710	34,857		11,381
(PROVISION) BENEFIT FOR INCOME TAXES		(1,218)		(4,574)	1,291		7,558
NET INCOME	\$	219	\$	136	\$ 36,148	\$	18,939
NET INCOME PER SHARE	-						
Basic	\$	0.01	\$	0.01	\$ 1.78	\$	0.97
Diluted	\$	0.01	\$	0.01	\$ 1.67	\$	0.92
WEIGHTED AVERAGE NUMBER OF SHARES							
Basic		20,474		19,984	20,362		19,433
Diluted		21,633		21,106	21,588		20,603

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:

<u>Interest</u>, <u>net</u>: 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.

<u>Stock compensation expense</u>: 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.

<u>Intangible asset amortization expense</u>: 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.

<u>Depreciation expense</u>: 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.

<u>Restructuring, strategic transaction and integration</u>: 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.

<u>Adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair market value</u>: 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.

<u>Bargain purchase gain</u>: We may incur a bargain purchase gain on certain acquisitions if the fair market value of the identifiable assets acquired and liabilities assumed, net of deferred taxes exceeds the total consideration paid. We exclude such gains as they are related to acquisitions and have no direct correlation to the operation of our ongoing business.

<u>Change in fair value of contingent earn-out</u>: 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.

Adjusted Diluted EPS excludes from diluted EPS, tax, interest, net, stock compensation expense, intangible asset amortization expense, restructuring, strategic transaction and integration, adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair market value, bargain purchase gain, which was tax free, and change in fair value of

contingent earn-out. We apply our GAAP consolidated effective tax rate to our non-GAAP financial measures, other than when the underlying item has a materially different tax treatment.

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) (Continued)

(In thousands, except per share data)

		Adjuste	l EBITDA	
		d		
		2018		2017
GAAP net income	\$	219	\$	136
Non-GAAP adjustments:				
Interest, net		(947)		123
Stock compensation expense		6,232		4,582
Depreciation and amortization expense		19,161		17,606
Restructuring, strategic transaction and integration		24,012		18,711
Adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair market value		_		11,180
Bargain purchase gain		_		(8,534)
Change in fair value of contingent earn-out		18,500		7,000
Provision for income taxes		1,218		4,574
Total non-GAAP adjustments		68,176		55,242
Adjusted EBITDA	\$	68,395	\$	55,378
	A	Adjusted diluted	earnings _I	er share
			nths ende	1
	-	2018		2017
GAAP diluted earnings per share	\$	0.01	\$	0.01
Non-GAAP adjustments:				
Interest, net		(0.04)		0.01
Stock compensation expense		0.29		0.22
Amortization expense		0.19		0.17
Restructuring, strategic transaction and integration		1.11		0.89
Adjustment to reverse the cost recognition related to the purchase accounting write-up of inventory to fair market value		_		0.53
Bargain purchase gain		_		(0.40)
Change in fair value of contingent earn-out		0.86		0.33
Estimated income tax impact from adjustments		(0.57)		(0.64)
Adjusted diluted earnings per share	\$	1.85	\$	1.12

ICU Medical, Inc. and Subsidiaries Reconciliation of GAAP to Non-GAAP Financial Measures - Fiscal Year 2018 Outlook (Unaudited)

(In millions, except per share data)

	Low E	End of Guidance	High End of Guidance			
GAAP net income	\$	56	\$	65		
Non-GAAP adjustments:						
Interest, net		(3)		(3)		
Stock compensation expense		24		24		
Depreciation and amortization expense		74		74		
Restructuring, strategic transaction and integration		105		105		
Change in fair value of contingent earn-out		21		21		
Provision for income taxes		3		4		
Total non-GAAP adjustments		224		225		
Adjusted EBITDA	\$	280	\$	290		
GAAP diluted earnings per share	\$	2.59	\$	2.99		
Non-GAAP adjustments:						
Interest, net	\$	(0.12)	\$	(0.12)		
Stock compensation expense	\$	1.13	\$	1.13		
Amortization expense	\$	0.75	\$	0.75		
Restructuring, strategic transaction and integration	\$	4.88	\$	4.88		
Change in fair value of contingent earn-out	\$	0.95	\$	0.95		
Estimated income tax impact from adjustments	\$	(1.73)	\$	(1.73)		
Adjusted diluted earnings per share	\$	8.45	\$	8.85		

ICU Medical, Inc. and Subsidiaries Reconciliation of GAAP to Non-GAAP Financial Measures - Fiscal Year 2019 Outlook (Unaudited)

(In millions, except per share data)

	Low End	l of Guidance	High En	d of Guidance
GAAP net income	\$	129	\$	147
Non-GAAP adjustments:				
Interest, Net		(4)		(4)
Stock compensation expense		24		24
Depreciation and amortization expense		85		85
Restructuring, strategic transaction and integration		45		45
Provision for income taxes		36		43
Total non-GAAP adjustments		186		193
Adjusted EBITDA	\$	315	\$	340

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ICR, Inc. John Mills, Partner (646) 277-1254