

**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 11, 2021



Acutus Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-39430

(Commission File Number)

45-1306615

(IRS Employer
Identification No.)

**2210 Faraday Ave., Suite 100
Carlsbad, CA**

(Address of Principal Executive Offices)

92008

(Zip Code)

Registrant's Telephone Number, Including Area Code: (442) 232-6080

Not Applicable

(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(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001	AFIB	The Nasdaq Stock Market LLC

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.

On November 11, 2021, the Company issued a press release announcing its financial results for the fiscal quarter ended September 30, 2021. A copy of this press release is attached as Exhibit 99.1 to this current report on Form 8-K.

Also on November 11, 2021, the Company hosted a conference call and webcast to discuss its financial results for the fiscal quarter ended September 30, 2021. A copy of the transcript for the conference call and webcast is furnished as Exhibit 99.2 and is incorporated herein by reference.

The information under Item 2.02 in this current report on Form 8-K and the related information in the exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”) or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated November 11, 2021 regarding financial results for the quarter ended September 30, 2021
99.2	Transcript of conference call and webcast conducted on November 11, 2021
104.0	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Acutus Medical, Inc.

Date: November 12, 2021

By: /s/ Vince Burgess
Vince Burgess
President and Chief Executive Officer

Acutus Medical Reports Third Quarter 2021 Financial Results

Carlsbad, Calif. – November 11, 2021 – Acutus Medical, Inc. (“Acutus” or the “Company”) (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today reported results for the third quarter of 2021.

Recent Highlights:

- Significant progress was achieved in our three core technology categories:
 - Left heart access: Revenues advanced three-fold in the third quarter versus prior year; initiated launch in our Europe and UK direct businesses
 - Mapping and therapy guidance: Initiated limited release of groundbreaking software upgrade AcQMap 8 with automated region of interest locator
 - Therapy: Initiated Pulsed Field Ablation (PFA) CE Mark study with first cases in Prague, Czech Republic
- Reported revenue of \$4.6 million in the third quarter of 2021, compared to \$3.2 million in the same quarter last year, led by increased procedure volumes and adoption of AcQMap globally
- Ended the third quarter with an installed base of 71 AcQMap mapping consoles. Within the quarter, several consoles were repositioned to different hospitals to drive higher utilization rates and procedure volumes

“During the quarter, we further strengthened our portfolio and market position in our left heart access, mapping and therapy guidance, and therapy categories,” said Vince Burgess, President & CEO of Acutus. “Our innovative left heart access product line has been very well received by electrophysiologists and structural heart specialists, and we continue to expand our product offering in this area. In mapping and therapy guidance, our software team delivered a first-in-the-industry mapping software upgrade with automated region of interest locators that helps physicians better tailor their therapy for each patient while minimizing destruction of healthy tissue. In therapy, we continued to install therapeutic ablation systems in Europe and the U.S. in support of our EU market launch and clinical trial activities, and now have nearly 40 of these systems in place. We also made significant strides with our integrated PFA therapy system allowing us to initiate enrollment in our Pulsed Field Ablation CE mark trial this week in the Czech Republic.”

Mr. Burgess continued “While we have made meaningful progress advancing our pipeline and technology leadership strategy, we have seen ongoing challenges in the external environment as well as gaps in our own commercial execution. With end-markets stabilizing in the fourth quarter, we are intensifying our commercial focus to drive higher account penetration and expanded product adoption across all three of our technology categories.”

Third Quarter 2021 Financial Results

Revenue was \$4.6 million for the third quarter of 2021, compared to \$3.2 million in the third quarter last year. The improvement over the same quarter last year was driven by increased direct sales of Acutus disposables and higher procedure volumes, as well as increased distributor sales through the Company’s partner, Biotronik. Gross margin on a GAAP basis was negative 86% for the third quarter of 2021, compared with negative 62% in the same quarter last year. The change was driven by unfavorable product and geographic mix. We continue to make significant investments in our manufacturing infrastructure to support rapid adoption of our broad product portfolio and to position us to scale in-house production as our business grows. As production volumes increase over time and we recognize the benefits of cost optimization initiatives, we expect our gross margin to improve.

Operating expenses on a GAAP basis were \$23.2 million for the third quarter of 2021, compared with \$24.3 million in the same quarter last year. The decrease was primarily driven by a change in fair value of the contingent consideration related to the acquisition of Rhythm Xience, partially offset by increases driven by the expansion of Acutus’ research and development team.

Net loss on a GAAP basis was \$28.5 million for the third quarter of 2021 and net loss per share was \$0.94 on a weighted average basic and diluted outstanding share count of 30.5 million, compared to \$31.2 million and a net loss per share of \$1.95 on a weighted average basic and diluted outstanding share count of 16.1 million in the same period of the prior year. Excluding amortization of acquired intangibles, non-cash stock-based compensation expense, remeasurement of the warrant liability, and changes in the fair value of contingent consideration, the Company’s non-GAAP net loss for the third quarter of 2021 was \$26.7 million, or \$0.87 per share, compared to \$21.0 million, or \$0.90 per share, after giving effect to the pro forma conversion of convertible preferred stock for the third quarter of 2020.

Cash, cash equivalents, marketable securities and restricted cash were \$134.7 million as of September 30, 2021. Our secondary equity offering, which was completed in July, resulted in additional net cash proceeds of \$82.7 million.

Outlook and COVID-19

Headwinds associated with COVID-19 have moderated in recent weeks; however, there remains meaningful uncertainty - and limited precedent - to predict the duration or sustainability of a recovery. Management continues to view the current situation with COVID-19 as being fluid, and the potential impact on the Company's business from hospital and government actions in response to potential resurgences in COVID-19 cases, COVID-19-related hospital admissions, restrictions on lab access and new technology assessments and hospital staffing shortages are all factors that could influence performance for the foreseeable future. Taking into consideration year-to-date results, external factors, and business performance, management now projects full year sales to range between \$17.0 and \$17.5 million.

Non-GAAP Financial Measures

This press release includes references to non-GAAP net loss and non-GAAP net loss per share, which are non-GAAP financial measures, to provide information that may assist investors in understanding the Company's financial results and assessing its prospects for future performance. The Company believes these non-GAAP financial measures are important indicators of its operating performance because they exclude items that are primarily non-cash accounting line items unrelated to, and may not be indicative of, the Company's core operating results. These non-GAAP financial measures, as Acutus calculates them, may not necessarily be comparable to similarly titled measures of other companies and may not be appropriate measures for comparing the performance of other companies relative to the Company. These non-GAAP financial results are not intended to represent and should not be considered to be more meaningful measures than, or alternatives to, measures of operating performance as determined in accordance with GAAP. Non-GAAP net loss is defined as net loss before income taxes, adjusted for stock-based compensation, amortization of acquisition-related intangibles, acquisition related costs, discontinued operations, asset impairments, non-operating items, restructuring charges, stock repurchases and other adjustments. To the extent such non-GAAP financial measures are used in the future, the Company expects to calculate them using a consistent method from period to period. A reconciliation of the most directly comparable GAAP financial measure to the non-GAAP financial measure has been provided under the heading "Reconciliation of GAAP Results to Non-GAAP Results" in the financial statement tables attached to this press release.

Webcast and Conference Call Information

Acutus will host a conference call to discuss the third quarter 2021 financial results after market close on Thursday, November 11, 2021 at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time. The conference call can be accessed live over the phone (833) 570-1131 for U.S. callers or (914) 987-7078 for international callers, using conference ID: 7373938 . The live webinar can be accessed at <https://ir.acutusmedical.com>.

About Acutus Medical, Inc.

Acutus is an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Acutus is committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more efficiently and effectively. Through internal product development, acquisitions and global partnerships, Acutus has established a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products that provide its customers with a complete solution for catheter-based treatment of cardiac arrhythmias. Founded in 2011, Acutus is based in Carlsbad, California.

Caution Regarding Forward-Looking Statements

This press release includes statements that may constitute "forward-looking" statements, usually containing the words "believe," "estimate," "project," "expect" or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to continue to manage expenses and cash burn rate at sustainable levels, continued acceptance of its products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase the Company's systems and the timing of such purchases, competitive factors, changes resulting from healthcare policy in the United States and globally, including changes in government reimbursement of procedures, dependence upon third-party vendors and distributors, timing of regulatory approvals, the impact of the coronavirus (COVID-19) pandemic and Acutus' response to it, and other risks discussed in the Company's periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, Acutus undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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Acutus Medical, Inc.
Consolidated Balance Sheets

<i>(in thousands, except per share amounts)</i>	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 58,492	\$ 25,234
Marketable securities, short-term	71,962	105,839
Restricted cash	150	150
Accounts receivable	4,190	2,160
Inventory	14,962	12,958
Prepaid expenses and other current assets	6,045	5,047
Total current assets	155,801	151,388
Marketable securities, long-term	4,061	8,726
Property and equipment, net	14,595	12,356
Right-of-use assets, net	4,682	1,669
Intangible assets, net	5,173	5,653
Goodwill	12,026	12,026
Other assets	1,086	717
Total assets	\$ 197,424	\$ 192,535
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,417	\$ 8,266
Accrued liabilities	9,398	7,308
Contingent consideration, short-term	1,900	5,400
Operating lease liabilities, short-term	466	933
Total current liabilities	18,181	21,907
Operating lease liabilities, long-term	4,695	1,134
Long-term debt	40,043	39,011
Contingent consideration, long-term	800	3,900
Other long-term liabilities	18	—
Total liabilities	63,737	65,952
Stockholders' equity		
Preferred stock, \$0.001 par value	—	—
Common stock, \$0.001 par value	28	28
Additional paid-in capital	581,133	487,290
Accumulated deficit	(447,434)	(361,015)
Accumulated other comprehensive income (loss)	(40)	280
Total stockholders' equity	133,687	126,583
Total liabilities and stockholders' equity	\$ 197,424	\$ 192,535

Acutus Medical, Inc.
Consolidated Statements of Operations and Comprehensive Loss

<i>(in thousands, except share and per share amounts)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Revenue	\$ 4,601	\$ 3,173	\$ 12,901	\$ 5,890
Costs and operating expenses:				
Cost of products sold	8,539	5,141	22,986	10,998
Research and development	9,299	8,343	27,843	24,492
Selling, general and administrative	15,805	15,833	47,658	35,193
Change in fair value of contingent consideration	(1,953)	118	(3,364)	(1,466)
Total costs and operating expenses	31,690	29,435	95,123	69,217
Loss from operations	(27,089)	(26,262)	(82,222)	(63,327)
Other income (expense):				
Change in fair value of warrant liability	—	(3,683)	—	(5,555)
Interest income	19	23	88	393
Interest expense	(1,441)	(1,366)	(4,285)	(4,090)
Total other expense, net	(1,422)	(5,026)	(4,197)	(9,252)
Loss before income taxes	(28,511)	(31,288)	(86,419)	(72,579)
Income tax benefit	—	—	—	—
Net loss	\$ (28,511)	\$ (31,288)	\$ (86,419)	\$ (72,579)
Other comprehensive income (loss)				
Unrealized loss on marketable securities	(13)	(9)	(3)	(50)
Foreign currency translation adjustment	(183)	78	(317)	147
Comprehensive loss	\$ (28,707)	\$ (31,219)	\$ (86,739)	\$ (72,482)
Net loss per common share, basic and diluted	\$ (0.94)	\$ (1.95)	\$ (2.99)	\$ (12.36)
Weighted average shares outstanding, basic and diluted	30,460,466	16,080,467	28,890,382	5,870,861

Acutus Medical, Inc.
Consolidated Statements of Cash Flows

(in thousands)	Nine Months Ended September 30,	
	2021	2020
	(unaudited)	
Cash flows from operating activities		
Net loss	\$ (86,419)	\$ (72,579)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	4,227	1,754
Amortization of intangible assets	480	330
Stock-based compensation expense	10,263	9,272
Amortization of premiums/(accretion of discounts) on marketable securities, net	1,011	113
Amortization of debt issuance costs	1,032	518
Amortization of right-of-use assets	496	507
Change in fair value of warrant liability	—	5,555
Change in fair value of contingent consideration	(3,364)	(1,466)
Changes in operating assets and liabilities:		
Accounts receivable	(2,030)	(1,630)
Inventory	(2,004)	(1,865)
Prepaid expenses and other current assets	(59)	(2,729)
Other assets	(369)	(387)
Accounts payable	(1,813)	753
Accrued liabilities	1,862	1,423
Operating lease liabilities	(432)	(615)
Other long-term liabilities	18	8
Net cash used in operating activities	(77,101)	(61,038)
Cash flows from investing activities		
Purchases of available-for-sale marketable securities	(70,020)	(108,528)
Sales of available-for-sale marketable securities	8,590	17,095
Maturities of available-for-sale marketable securities	98,507	45,000
Purchases of property and equipment	(6,587)	(7,822)
Net cash provided by (used in) investing activities	30,490	(54,255)
Cash flows from financing activities		
Payment of deferred offering costs	(572)	—
Payment of contingent consideration	(3,152)	(2,636)
Proceeds from the issuance of common stock, net of issuance costs	82,664	166,286
Proceeds from stock options exercises	703	350
Proceeds from Employee Stock Purchase Plan	440	—
Net cash provided by financing activities	80,083	164,000
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(214)	143
Net change in cash, cash equivalents and restricted cash	33,258	48,850
Cash, cash equivalents and restricted cash, at the beginning of the period	25,384	9,602
Cash, cash equivalents and restricted cash, at the end of the period	\$ 58,642	\$ 58,452

Acutus Medical, Inc.
Reconciliation of GAAP Results to Non-GAAP Results
(Unaudited)

Three Months Ended September 30, 2021	Cost of products sold	Research and development	Selling, general and administrative	Loss from operations	Other expenses, net	Net loss	Basic and diluted EPS
Reported	\$ 8,539	\$ 9,299	\$ 15,805	\$ (27,089)	\$ (1,422)	\$ (28,511)	\$ (0.94)
Amortization of acquired intangibles	(155)	—	(5)	160	—	160	0.01
Stock-based compensation	(243)	(567)	(2,767)	3,577	—	3,577	0.12
Change in fair value of contingent consideration	—	—	—	(1,953)	—	(1,953)	(0.06)
Adjusted	\$ 8,141	\$ 8,732	\$ 13,033	\$ (25,305)	\$ (1,422)	\$ (26,727)	\$ (0.87)

Three Months Ended September 30, 2020	Cost of products sold	Research and development	Selling, general and administrative	Loss from operations	Other expenses, net	Net loss	Basic and diluted EPS
Reported	\$ 5,141	\$ 8,343	\$ 15,833	\$ (26,262)	\$ (5,026)	\$ (31,288)	\$ (1.95)
Adjustment for assumed conversion of convertible preferred stock	—	—	—	—	—	—	0.61
Amortization of acquired intangibles	—	—	(110)	110	—	110	—
Stock-based compensation	(127)	(239)	(6,008)	6,374	—	6,374	0.27
Change in fair value of contingent consideration	—	—	—	118	—	118	0.01
Change in fair value of warrant liability	—	—	—	—	3,683	3,683	0.16
Adjusted	\$ 5,014	\$ 8,104	\$ 9,715	\$ (19,660)	\$ (1,343)	\$ (21,003)	\$ (0.90)

	Three Months Ended September 30,	
	2021	2020
Denominator		
Weighted average shares of common stock outstanding used in GAAP per share calculations	30,460,466	16,080,467
Adjustments to reflect the assumed conversion of convertible preferred stock ⁽¹⁾	—	7,205,624
Shares used in non-GAAP per share calculations	30,460,466	23,286,091

- (1) Assumes the conversion of outstanding shares of convertible preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period or their issuance dates, if later.

Acutus Medical, Inc.
Key Business Metrics

Installed Base

The total installed base as of September 30, 2021 and 2020 is set forth in the table below:

	As of September 30,	
	2021	2020
	(unaudited)	
Acutus Direct		
U.S.	42	29
Outside U.S.	18	15
Total Acutus Direct	60	44
Biotronik	11	5
Total installed base	71	49

The net increase in installed base for the three and nine months ended September 30, 2021 and 2020, exclusive of transfers between Acutus and Biotronik, is set forth in the table below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Acutus Direct				
U.S.	—	9	5	19
Outside U.S.	—	2	4	3
Total Acutus Direct	—	11	9	22
Net systems to Biotronik	1	—	4	—
Total net system placements	1	11	13	22

Revenue

The following table sets forth the Company's revenue for disposables, systems and service/other for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Month Ended September 30,		Nine Month Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Acutus Direct				
Disposables	\$ 2,437	\$ 1,680	\$ 7,036	\$ 3,599
Systems	341	965	1,626	1,485
Service/Other	123	29	191	47
Total Acutus direct revenue	2,901	2,674	8,853	5,131
Distribution agreements	1,700	499	4,048	759
Total revenue	\$ 4,601	\$ 3,173	\$ 12,901	\$ 5,890

The following table provides revenue by geographic location for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Acutus Direct				
United States	\$ 2,164	\$ 1,790	\$ 5,976	\$ 3,103
Outside the United States	737	884	2,877	2,028
Total Acutus direct revenue	2,901	2,674	8,853	5,131
Distribution Agreements				
United States	25	77	281	92
Outside the United States	1,675	422	3,767	667
Total revenue through distribution agreements	1,700	499	4,048	759
Total revenue	\$ 4,601	\$ 3,173	\$ 12,901	\$ 5,890

REFINITIV STREETEVENETS

EDITED TRANSCRIPT

Q3 2021 Acutus Medical Inc Earnings Call

EVENT DATE/TIME: NOVEMBER 11, 2021 / 9:30PM GMT

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NOVEMBER 11, 2021 / 9:30PM GMT, Q3 2021 Acutus Medical Inc Earnings Call

CORPORATE PARTICIPANTS**Vincent J. Burgess** *Acutus Medical, Inc. - President, CEO & Director***David Harrison Roman** *Acutus Medical, Inc. - Senior VP & CFO***CONFERENCE CALL PARTICIPANTS****Caroline Corner** *Westwicke an ICR Company***Robert Justin Marcus** *JPMorgan Chase & Co, Research Division - Analyst***Malgorzata Maria Kaczor** *Andrew William Blair & Company L.L.C., Research Division - Partner***William John Plovanic** *Canaccord Genuity Corp., Research Division - Analyst***Marie Yoko Thibault** *BTIG, LLC, Research Division - MD and Medical Technology and Digital Health Analyst***Amit Hazan** *Goldman Sachs Group, Inc., Research Division - Equity Analyst***PRESENTATION****Operator**

Good day, and thank you for standing by. Welcome to the Acutus Medical, Inc. Third Quarter 2021 Earnings Conference Call. At this time, all participants are in listen-only mode. After the speaker's presentation, there will be a question-and-answer session. (Operator Instructions) I would now like to hand the conference over to Caroline Corner of Investor Relations. Please go ahead.

Caroline Corner

Thank you, operator. Welcome to Acutus' Third Quarter 2021 Earnings Call. Joining me on today's call are Vince Burgess President and Chief Executive Officer; and David Roman, Chief Financial Officer.

This call will include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements made on this call do not relate to matters of historical fact should be considered forward-looking statements. Factors that may cause results to differ from these forward-looking statements are discussed under the forward-looking statements section in the press release attached to an exhibit to Acutus' Form 8-K filed with the SEC today and are also discussed in more detail under the Risk Factors section in Acutus' most recent filings with the SEC, including the risk factors described in Acutus' Form 10-K.

Any forward-looking statements provided during this call, including projections for future performance are based on management's expectations as of today. Acutus undertakes no obligation to update these statements, except as required by applicable law. Acutus' press release for third quarter 2021 results is also available on Acutus' website, www.acutusmedical.com under the Investors section and includes additional details about Acutus' financial results. Acutus' website also has Acutus' SEC filings, which you're encouraged to review. A recording of today's call will be available on the Acutus website by 5:00 p.m. Pacific Time. Now, I'd like to turn the call over to Vince for his comments on third quarter 2021 business highlights.

Vincent J. Burgess *Acutus Medical, Inc. - President, CEO & Director*

Thank you, Caroline, and good afternoon to everyone joining us on the call today. During today's call, I will update you on our key strategic priorities as well as some recent clinical, commercial, and market developments. I will also comment on our third quarter results, provide some perspective on market dynamics, and provide an update on what

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we are seeing in our business today. David will follow-up with details on our financial and operational results as well as our outlook for the rest of the year.

Before I dive into commentary on the external environment and our Q3 operating results, I'd like to focus on key accomplishments during the quarter by our team in each of our 3 core technology areas, left heart access, mapping and therapy guidance, and therapy. Our left heart access product line continues to be very well received by electrophysiologists and structural heart specialists as we continue to rapidly build out the breadth of the product line.

Over the past year, we have refined and expanded this product line from a narrow offering of just 5 SKUs to over 20 SKUs today. We are seeing an encouraging adoption curve here with Q3 2021 total septal crossing revenues threefold higher than the same quarter last year.

In mapping and therapy guidance, our software team delivered a unique-in-the-industry mapping software capability that automatically calls out regions of interest to the benefit of our mappers and their physician customers, rapidly revealing new insights into cardiac signals that will help physicians better tailor their therapy for each patient while minimizing destruction of healthy tissue. We believe this feature will be particularly helpful in the large and growing population of patients with persistent and long standing persistent atrial fibrillation, where ablation results remain challenging.

In therapy, our AcQBlate Force Sensing Ablation Catheter and System is gaining commercial traction in Europe. This product line is now annualizing at around \$1 million, and we expect further growth here in Q4. Our teams in the U.S. and EU, as well as our partner Biotronik, have made excellent progress in installing these therapy systems. By the end of this week, we expect to have 40 therapeutic ablation systems installed worldwide for commercial use and in support of clinical trial activity. These ablation systems are the workhorse engine behind our AcQBlate Force Sensing Ablation Catheter and are a leading indicator of adoption.

In support of our efforts to gain RF ablation approval in the U.S., I can also update you that enrollment in our right atrial flutter ablation trial is going well, and we expect to complete enrollment and submission to allow for approval in the U.S. by the end of 2022 or early 2023. In addition to pursuing a flutter indication, we plan to imminently enroll our first patient in the U.S. IDE for RF ablation of atrial fibrillation. This trial involves a 1-year follow-up, and we will keep you apprised of our progress.

Also in therapy, as announced today, we treated our first patient in our Pulsed Field Ablation CE Mark study in the Czech Republic. We had previously discussed first enrollment by the end of this year, and given the success of our animal studies, confidence of our physician investigators, quality of our product, and incredible focus from our internal teams, we have achieved this critical milestone.

The AcQForce PFA CE Mark Study will enroll up to 60 patients and also serve as a foundation for our U.S. IDE study application. We are not yet providing guidance on Pulsed Field Ablation approval timelines, but we are very encouraged by program developments.

Diving a little deeper into our approach to PFA. Unlike the vast majority of competitor PFA programs under development that are focused on pulmonary vein isolation alone with large format, so called single shot catheters, we are advocating for a more tailored, patient specific application of PFA energy by utilizing our focal AcQBlate Force Sensing Ablation Catheter as the therapeutic delivery device.

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This tailored approach will be further enhanced when combined with our AcQMap mapping system that also facilitates identification of target treatment areas outside of the pulmonary veins, which is thought to be essential to more effectively treat patients with complex tachycardias and persistent and long-standing persistent atrial fibrillation.

This strategy is a deliberate choice on our end to enable a fast therapy platform on a fast imaging platform to guide therapy in line with our mission to treat AF with a personalized approach to improve outcomes.

So in summary, a careful review of our current and future product lines reveals our tenacious focus on innovation is bearing fruit and signals a very bright future for the company. We are seeing strong performance in our left heart access and therapy categories, which will become increasingly important revenue contributors over time.

Our mapping and therapy guidance business has progressed somewhat slower than expected, and we are actively addressing the factors contributing to the adoption rate, including upgraded software to improve physician experience and enhanced training for our teams.

With that, I'll turn to an update on the external environment as well as our recent performance. During our last earnings call in August, we described the operating landscape as very fluid, and this is exactly how things played out. In the U.S., we saw COVID related shutdowns in several parts of the country, including Arizona, Florida, and Nevada, where we happen to have a high concentration of mapping and left heart access customers.

In Europe, we saw extended cath lab shutdowns, partly due to managing COVID risk as well as longer than usual vacations. In many instances, we found that labs, where we have business in Europe were closed for as long as 6 to 8 weeks versus the normal seasonal pattern where labs are largely shuttered for 3 to 5 weeks.

The combination of COVID impacts, including peak resurgence, extended seasonality, broader hospital restrictions and staffing shortages created greater-than-expected headwinds in the quarter. While we saw momentum in procedure volumes in late September, the magnitude of the rebound was insufficient to offset a lower-than-planned installed base, lower capital sales and conversions and procedure disruptions. We have been actively monitoring market trends, and we are seeing general stability here in Q4.

Turning to Q3 results. We generated revenue of \$4.6 million, representing good growth versus the prior year third quarter and essentially flat compared to the second quarter of 2021. Year-over-year growth was driven by higher procedure volumes globally and an increased capital equipment revenue.

On a sequential basis, higher capital sales offset a decline in disposable sales tied to COVID-19 related procedure deferrals and extended seasonality. We ended the quarter with an installed base of 71 AcQMap systems. During the quarter, we made the strategic decision to remove and reposition certain systems with below target utilization or where key physician users had relocated to a new geography.

As we focus our commercial strategy, we are also looking to optimize console placement. Targeting the right accounts where we can drive higher adoption will allow us to optimize utilization of our cash and human resources.

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This does not mean that we won't continue to grow our installed base. That simply means that we will be extraordinarily disciplined in where we make the considerable investment to install a new system.

In the U.S., the pace of new system installations in Q3 trailed our internal expectations. We also are still seeing lab access restrictions and certain hospital policies to limit new technology evaluations as well as lengthy administrative processes. This is regardless of strong physician support in a number of centers.

Further, as procedure volumes have rebounded post COVID surges, the market generally seems to be favoring technology familiarity and predictable patient throughput to clear patient backlogs resulting from COVID disruptions. In Europe, we saw seasonality play a major role in installed base trends.

Moving to global procedures. We saw over 50% growth versus last year's third quarter, but a decline sequentially versus Q2 of this year related to factors previously discussed. In the U.S., we saw improvement in volumes month-by-month during the quarter. Procedure volumes in Europe were stable throughout the quarter at a lower level than Q2. All told, we are encouraged by what we are seeing across the board with respect to procedure volumes here in Q4.

Overall, while our business trajectory has improved, I am not satisfied with our performance or commercial execution. The external environment has proven a major headwind and the impact that the pandemic has had on procedure volumes, hospital access, recruiting and new technology adoption has been more severe than expected. At the same time, we have not fully executed on our own internal initiatives.

We recognize this as a management team and are responding accordingly. In the U.S., we have centered our business around what we call Power Pods, which are regions where we have a high concentration of accounts, utilization, and correspondingly Acutus representation. This has led to our strong performance in the Southeastern and Southwestern United States. The U.K. and parts of Central Europe take on a similar profile with strength in concentrated areas.

Going forward, the key is to replicate and expand this model. This strategy will drive long-term success and deeper account penetration, but will also likely take longer to scale than we had initially anticipated. In no way does the pace of our ramp shake our conviction and the value we can provide our physician customers and patients. As we build this company for the long term, we remain steadfast in our mission to bring differentiated and highly valuable technology to this large and growing market. I will be happy to cover this in more detail in the Q&A. And I'll now turn it over to David for our financial results. David?

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

Thank you, Vince, and good afternoon, everyone. During my remarks today, I will provide details on third quarter 2021 operating results as well as our outlook for the rest of the year. As Vince previously mentioned, our revenues for the third quarter of 2021 were \$4.6 million, up from \$3.2 million in Q3 2020. Sales in our direct businesses of approximately \$2.9 million increased from \$2.7 million in the third quarter of 2020.

On a sequential basis, our direct businesses declined approximately \$620,000 due to procedure volume headwinds related to COVID-19, lower capital conversion, extended cath lab closures in Europe and lower new installations.

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Offsetting some of the pressure in our direct business was strengthen our Biotronik partnership. Revenue through distribution agreements of approximately \$1.7 million compared with \$499,000 in the prior year's third quarter, driven by both disposable and capital sales.

As a reminder, this business was relatively flat sequentially in the second quarter as we did not register any capital sales in Q2. In Q3, we saw Biotronik convert much of their installed base to full capital purchases, reflecting their long-term commitment to growing the business in key markets.

Non-GAAP gross margin was negative 77% for the third quarter of 2021 compared with negative 58% in the third quarter of 2020. The year-over-year decline in our non-GAAP gross margin largely relates to mix with a higher proportion of our sales in this year's third quarter coming from capital and sales through distribution partners.

Going forward, improving our gross margin will depend on several factors, the most important of which is scale. We have invested and are built to support long-term meaningful growth, which results in a heavy overhead burden today. As we grow the business, that fixed cost will get absorbed across higher volumes.

Secondary to scale is product mix between disposables and capital as well as mix among our operating segments. Lastly, we are intensely focused on variables we can control such as manufacturing yields, labor costs and component spend.

Non-GAAP operating expenses were \$21.8 million in the third quarter of 2021 compared with \$17.8 million for the same period last year. The year-over-year increase in non-GAAP operating expenses was primarily related to investments in the AcQBlate Force-Sensing Ablation Catheter, our PFA program, software development, investments in our commercial organization, and public company-related costs.

Our non-GAAP operating expenses have been roughly flat on a sequential basis the past 4 quarters as we reallocate resources to fund growth programs. We remain very focused on expense management and optimizing our investments.

Excluding specified items, our non-GAAP net loss for the third quarter of 2021 was \$26.7 million or \$0.87 per share compared to a non-GAAP net loss of \$21 million for the third quarter of 2020 or \$0.90 per share, after giving effect to the pro forma conversion of our convertible preferred stock. Our total cash balance at the end of the third quarter of 2021 was \$134.7 million.

Looking to the remainder of 2021, I'd like to provide some further detail regarding our outlook. Over the course of this year, we have consistently talked about 5 key sales growth drivers, and I'll provide a further update today.

The first is capital sales. Total revenue, excluding service and rent in the first half of the year was approximately \$1.8 million. Q3 revenue totaled \$1.5 million. And based on what we have already generated here in Q4, we expect the second half to at least match the first half of the year.

Second is manufacturing yields. We have resolved the majority of back orders in key product lines and are aligning our production volumes to meet demand. Third is new product launches. Across our portfolio, we have launched several new products this year, most notably AcQBlate in Europe and transeptal crossing devices in the U.S. and

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Europe. These product categories generated around \$400,000 of revenue in Q1, about \$800,000 in each Q2 and Q3, and we expect further strength in Q4.

Fourth is a normalization of market conditions. We had assumed in our initial guidance that COVID related headwinds would dissipate throughout the year. This has not materialized as expected, and we have seen ongoing waves of COVID disruptions and recoveries. In addition, we are observing an overall more challenging environment for new market entrants due to hospital restrictions on new technology and ongoing macro disruptions.

The last key driver is improved commercial execution. With the revamped strategy earlier this year, we had planned for a more rapid improvement in execution. Vince discussed the status here in detail earlier in the call, and this is one of the major drivers included in our updated guidance.

Putting this all together, we now expect revenue to be in a range of \$17 million to \$17.5 million, reflecting our year-to-date results, the flow-through effect of a smaller than expected installed base and the commercial execution dynamics that we've discussed. We have taken a balanced stance on the evolution of the external environment and the pace at which we can drive improved sales execution. I will now turn the call back to Vince for closing remarks and to facilitate the Q&A.

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

Thank you, David. As I reflect on where the business stands today, I'm most encouraged by the proof points, reinforcing our view that this market is hungry for innovation and improved procedural efficiency and results and that our team is absolutely able to deliver it.

In particular, in Europe, where top-tier hospitals are using our complete product line, left heart access products, our mapping system and our ablation system in catheter to complete their entire procedure, start to finish with great results. This is happening in hotly contested bellwether accounts with entrenched competition.

The priority now is to replicate that success and scale our business at a more rapid pace. As we have said in the past, disruption will not be linear, and we are building this company to be a long-term industry leader.

As you have seen in the press lately, there is a tremendous amount of interest in EP, most notably in left heart access and advanced therapy. We are very, very pleased with our progress in developing novel technologies in these categories, further bolstered by our differentiated mapping system. We are sharpening our pencils in some key areas and look forward to updating you on our trajectory on future calls. We appreciate your continued interest and support, and we'll now open the call to your questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Robbie Marcus with JPMorgan.

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Robert Justin Marcus JPMorgan Chase & Co, Research Division - Analyst

Great. So 2 for me. Vince, maybe to start, what do you think it is that's preventing greater adoption? Is it that doctors aren't buying into the technology? Are people not getting the results? There's good data. It's been over a year since the IPO, and the launch has pretty much been flattish since then. So what is it that's preventing more utilization, especially having, I guess, some placements and then removal of some units. You have flat unit growth. I would have expected a lot more. So I would just love your color.

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

Yes. Thanks, Robbie. This is a complicated business, and you've got to get everything right in order to convert a physician and gain their regular utilization and start to ramp. I think the first issue I focused on is some of the hospitals we targeted early on were profiled expertly, and we knew very well who we were working with, and what their procedural approach was going to be, and how well we could and did fit in with their workflow and their philosophy around ablate and our diagnosis.

And we've had great results there. We have tens of physicians and hospitals where we're seeing really nice uptake and regular utilization. And some of the other places we targeted, I think we just -- #1, we might have missed the boat in terms of physician profiling and understanding the match of where we were in our journey in terms of refinement of all the different procedural nuances and approaches and also where they were, kind of where we were meeting them where they were. Were we installing in centers that wanted to stay with a standard kind of anatomical approach to their ablations. Or are we going into centers that didn't really accept that, that was necessarily good enough? And where those doctors and centers really committed to learning -- getting up the learning curve of a new technology in order to hopefully provide better outcomes and faster procedures.

It does take -- we do fundamentally change certain aspects of these procedures, and it does take a commitment to learn what those steps are and work them into your daily routine. I think we're getting better at that. We're getting -- we have much better clarity on how to ask those questions, the right questions, respectfully, physicians so that we suss that out early on in the process before we invest a lot of time, effort, energy to install a system and put people on the ground.

The other thing I have to say is we need to get better at onboard -- I'm sorry, onboarding our own people. When we bring them on as mappers or therapy managers and, in particular, salespeople and account managers. We're still learning how to hire and attract the right people for the job we have at hand.

This is not a maintenance milk run, account manager kind of a sales role. This is a business and market development role, and we need savages, people that have come in and brought new technologies into physician groups and hospitals, and work with those physicians to make the changes necessary to take it to the next level and attempt a new approach at these procedures.

And I think we're pretty self aware about that, and we're getting after it with our team, but these things take time. It has been a learning process for us. I think it's coming into much clearer focus, what we need to do, where we need to be and how we need to do it.

Robert Justin Marcus JPMorgan Chase & Co, Research Division - AnalystREFINITIV STREETEVENTS | www.refinitiv.com | [Contact Us](#)

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Maybe second question for David. The Street is sitting around \$50-ish million in sales for next year. My guess is that's probably high given the placements in the quarter and the run rate for fourth quarter. So should we be thinking something more like \$20 million, \$25 million for next year? Is that a good sort of trajectory? I know you haven't given official guidance yet.

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

So we're still in the process of finalizing our 2022 operating plan as you referenced. But let me give you some perspective on the key drivers that will help answer your question. So first and foremost, as Vince mentioned, we are steadfastly focused on our mission to continue to invest and transform EP as well as dramatically improve patient outcomes in the physician experience. That is very much top of mind as we look to 2022, and we think about our own operating plan.

As you look at 2021, our updated guidance contemplates roughly more than a doubling of sales when compared to 2020, a little bit more than a doubling. As you know, 2021 included several headwinds, such as COVID-19, enhanced seasonality. And of course, as we've discussed, the uneven sales performance.

As we think about 2022, from where we sit today, it's very likely we'll face some continued headwinds from COVID-19, whether those are direct in nature such as elective procedure volume disruptions or indirect, such as lab access and hospital restrictions. I think we and many have tried to predict kind of the end of COVID and a full normalization of market conditions. But from where we sit today, expecting that 2022 look something like 2019 and that the COVID cloud fully lift is probably premature.

So I think as you referenced, for our business specifically, we'll end 2021 with a lower than originally planned installed base, which will have a carryforward effect on our business next year because the installed base expands the user base, expands procedure volumes, expands disposable revenue.

That will be partially offset by some of the new product launches that we've discussed, which are now annualizing at a very nice level, septal crossing and AcQBlate, we're annualizing about \$3.2 million as of the third quarter. But all told, given all the moving parts in our business, given kind of the external and internal factors, we're probably about a year behind where we thought we would be in terms of sales and execution when compared to our view in March of this year. And we'll give full guidance and formal guidance, excuse me, in our fourth quarter call, which will be late February or early March.

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

If I could just follow-on with that, David. I think, Robbie, you also talked about the installed base. And one of the things, we definitely had planned and projected to have a larger increase in our installed base in Q3. We did make a very conscious decision. And these are kind of difficult painful decisions to remove and replace or reposition some of the -- less than 10 -- but still a meaningful number of consoles that were already in place, because the doctor or champion maybe had moved geography or we just weren't seeing the kind of traction we wanted to, or maybe we had the wrong commercial team on the ground. We're not -- an insufficient commercial team on the ground.

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We will ramp that growth back up. And this quarter alone in Q4, I believe, we have installed into 5 new centers already this quarter. The other thing I just want to reinforce the importance of and it's hard to reinforce the importance enough, is the fact that over the last 12 months, we have installed in the U.S., Europe, and through our Biotronik partner, about 40 ablation systems.

So this is the cubic force unit, the RF generator, the pump, and the stimulator. This is a very important potential revenue generator for us, not just for ablation, but really also across the board. As we talked about since day 1 as we've got to know each other. Mapping is really important, mapping, tied and intimately integrated with therapy is kind of the holy grail here, especially when you have a mapping system like ours and state of the art ablation system.

So to get 40 of these units installed over the last 12 months, I think I'm really proud of the team for doing that. And I think that is a very important kind of bellwether number for us to focus in on.

Operator

Our next question comes from Margaret Kaczor with William Blair.

Malgorzata Maria Kaczor Andrew William Blair & Company L.L.C., Research Division - Partner

I wanted to maybe follow-up a little bit more on '22 to start and kind of trying to get a good sense of what the visibility is around those capital sales and installed base growth. So following up on your comments around the time line being set for new technology sales and so on. Can those come back, I guess, early part of next year? Or is this kind of maybe getting pushed out 6 or 9 months as you guys figure out the Power Pods and the geographies and so on?

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

Yes, Margaret, thanks for the question. So some of those factors that we talked about with respect to new technology evaluation and administrative processes are potentially byproducts of COVID as well as the staffing shortages that you've heard extensively about in the industry.

And I think from where we sit today, putting a fine time line on when that's going to be resolved, isn't something we have visibility to do. So what -- as we look at our fourth quarter guidance and start to put together the plan for 2022, we are assuming that many elements of the external environment remain very similar to what we've seen over the recent past, clearly, not a repeat of the Delta variant impact or the 2020 COVID type dynamics with extended full shutdowns of hospitals. But reverting to a fully normalized environment is not something on which we have a lot of visibility right now, nor is something that we would count on.

To your point specifically about our business, we have identified and have segmented the Power Pods in our business where we do have the right staffing and a concentration of accounts, we are seeing very strong utilization, not just of our mapping system, but across the entire portfolio of products that are available.

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And in Europe, where there's a broader set of products available, the dynamic is similar, but I would expect the pace of new installations to probably be better than 2021 because this is a year where we are also going through the rationalization effort of repositioning consoles. But if you look at this year, our net installs were 4 in Q1, 8 in Q2, 1 in Q4 -- Q3, excuse me. Vince referenced that we've installed 5 systems to date here in Q4.

We may reposition some as we exit the year. So as you can see it's pretty uneven. This year had some extraordinary dynamics associated with it. But getting to a so-called normalized cadence in the end market is something that just hasn't been sustained over the course of this year. So assuming that we're going to have a normal 2022 just doesn't seem prudent right now.

Malgorzata Maria Kaczor Andrew William Blair & Company L.L.C., Research Division - Partner

No, fair enough. And then I had 2 other questions. One was around the Power Pod strategy. I'm trying to get a little bit of a sense of why those Pods maybe are doing better than others from a profile or service perspective on your part. And then as we think about that scale effort for and throughout '22, can you turn us up? Are there 2 Power Pods and those are going to CAGR? Any kind of color there for us would be useful.

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

Vince, do you want to take that one?

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

Yes, sure. Great question. What I would say is what we learned, and I think we alluded to this on an earlier call. One of the things we've learned over the last year or so is when you are bringing not just a mapping system, but a mapping system that has a physical catheter and a sheath, and now left heart access product line, and you have -- you need really, really good communication with a new user between the physician and the mapper.

When we onboard a new account, we need to have somebody at the table beside the physician, walking them through how to use the catheters, remind them what they're looking at on the screen. Talk about what they have seen other physicians do in certain situations and just kind of shepherd the procedure through, not just have a mapper driving that mapping system.

And as we think about the skill set that is required for that bedside person, it is typically somebody that has more of an interventional background. The world I come from on the interventional cardiology side, there are a number of other places we can hire from, peripheral markets, some of the structural heart companies out there. They have that skill set.

So as we think about the Power Pod, if you have that table side person who also has account management skills and you pair them up with a rockstar mapper or therapy manager, as we call them, and we have a cadre of those. We've been able to attract the best of the best therapy managers around the country and in Europe to drive our system.

But as you pair up that team, you can be very, very effective. But I think we understaffed that team initially. The second thing is that the way to scale this is to where, I think, rather than kind of pock mark the country with Pods

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here and there, it's going to be more cost-effective to the extent possible that you kind of radius or radiate out from those initial Power Pods.

And if you look at the history of our brethren in this industry, the leaders in this business, that's very much how they evolved over time over the last decade -- 2 decades as well is they really deployed a Pod strategy. I think we should have come to the sooner, but we are where we are, and we are now stopping on the accelerator to scale that approach.

Malgorzata Maria Kaczor Andrew William Blair & Company L.L.C., Research Division - Partner

And just last one on me. I mean the growth, obviously, in the new products, septal crossing, AcQBlate was really strong, good trajectory going into next year, that 40 units that are kind of ready for that at this point is good as well. But how should we think about that in terms of potential other new accounts that could get added to that or better utilization amongst the existing accounts for those 2 products versus others?

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

Yes. What I'd say what I'd say is septal crossing, it's really one of the first things you do in the procedure. And if you do it poorly, it can kind of muck up the whole procedure. And if you do it well, it can portend a really efficient procedure. So if you get in there, you get it right, it's a great calling card and entry point for introducing customers to our entire company, our product line, and our philosophy, and the passion that we bring to this business.

I think in the U.S., over half of our septal crossing customers currently, over half of our good high-volume customers don't have a mapping system yet. And believe me, when they get to know our people and they see how we think about innovation here, they very often are -- those customers are very high on our funnel list for systems that we hope to get installed in Q4 and next year.

So that's just a terrific business model for us. In terms of the ablation side of things, obviously, we are not commercial with ablation in the U.S. yet. As we roll out our clinical trial sites for the ablation trials we are doing, you might imagine that the large majority of those sites where we choose to do ablation trials are going to be sites that already have or about to take our mapping system. And that has its own set of effects.

In Europe, we are -- I think we're getting close to 1-to-1 in terms of sites where we have mapping consoles and sites where we have our therapy stack or system, as we call it, which again, includes the force generator, the RF generator, the pump. And as I said in my closing remarks, nothing helps me sleep better at night than when I look at some of the absolute blue-chip accounts in Europe that do not suffer fools.

They don't suffer products that aren't state of the art, have adopted our complete line of products. And they'll do virtually the entire procedure stem to stern using our technology, crossing, mapping, ablation. And as we scale that, I mean, that's got to be the model for us. That's clearly going to be the highest ROI for us and the most efficient use of our cash and other resources.

Operator

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Our next question comes from Doug Plovanic with Canaccord.

William John Plovanic Canaccord Genuity Corp., Research Division - Analyst

First, to start with, just you have 71 systems in the market right now. Just how many of those are under evaluation versus actually owned versus -- with either purchase or a use agreement?

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

David, do you want to take that?

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

Sure, Bill. So of the 70 -- let me just give you -- back up for a second for you. So the 71 units out there that are in the fields that are converted either permanent sale, catheter commitment, or rent is in the mid-20s.

William John Plovanic Canaccord Genuity Corp., Research Division - Analyst

So about mid-20s of those 71. And then so that means you have 45ish, 40, call it, evaluation systems. How should we -- and you've been moving some of those around? I think some of those have been out there a while as well at some of those accounts. How do we kind of think about either continuation of the rationalization program that you have ongoing versus kind of new sales, at least in the near term?

It sounds like -- my gut is we're going to have a little more of this rationalization. And then as we kind of start with the goal of finishing that out at the end of this year. And I just want to check on that.

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

I think that's a fair characterization, Bill. We'd expect probably a couple more to come out and be here in the fourth quarter. For the balance of them, we will continue, obviously, to work to convert those to either some sort of permanent place. Our goal is to drive utilization.

Capital sales obviously helped the top line. But if we have an account that is engaged and wants to utilize the system at a significant clip, we will figure out a placement program that makes sense for us and for them, such that we can continue to drive disposable utilization as well as drive ongoing proof points and build a consistent and strong user base.

So you look at the pool of capital that's out there, that sort of convertible, the \$45 million or so that you referenced. We will convert some of those to permanent placement, whether that's through a capital sale or some other model where we wouldn't recognize the upfront revenue. That's to be determined. But ultimately, we -- our goal is to create

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an ecosystem that facilitates utilization for our physician customers and work with administration to ensure we have a compliant and permanent way to get these systems placed.

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

Let me give you another perspective on this as well. Let's say, for example, each account is different, right? These are, at the end of the day, these Eps are heavily focused on procedures and working through their backlog of patients. So they want to do procedures, they want to do procedures with us.

If we look -- let's pick an example account where maybe we installed a couple 3, 4, 5 months ago, doctor #1, Champion #1 uses it maybe a couple of times a month. And we're okay with that, but it's not really the kind of ROI we want. Doctor #2, his colleague, kind of likes what he sees. But unlike Doctor #1, he wants to use a different ablation catheter with our system than the one Doctor #1 wants to use. But we don't have the right connectology and we're not validated with that catheter yet.

There's a pretty good subset. There's a very common catheter. We're delivering, I think, in the next few weeks, a new cable that will allow Doctor #2 to use the ablation catheter that he likes. So that's how we start to bring up that account or another account, the doctor #2 or even the initial doctor, the champion, just finds that he just has a hard time interpreting the images and figuring out his therapy plan based on our maps. Because our maps can be challenging to interpret and guide therapy on because a lot of times, we're mapping complex arrhythmias like Afib and it's chaos, and it's hard to interpret.

So we just launched AcQMap 8, our new mapping software, which I think we now have in all of our centers that has automated region of interest finders that helps the physicians actually understand what they're looking at and develop a therapy strategy much more quickly than they could before.

So every hospital that isn't at the procedure volumes that we want isn't necessarily going to be repositioned. Sometimes they're just waiting for those incremental improvements that we need to deliver in order to get people to bear hug us and start adopting.

William John Plovanic Canaccord Genuity Corp., Research Division - Analyst

I have 2 more bigger picture questions. Vince, the first one is, you just talked about the automatic region finder softer, which I think we saw back at HRS, if I remember correctly. What else in the product set, you're bringing the cable out for an ablation catheter. As you continue to develop the mapping software, you brought out a bunch of new products in access. Is there any 1 or 2 or 3 things that need to be brought in, a change that kind of opens the floodgates up?

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

Well, what I would say is the image interpretation region of interest finder is a big deal. In that same software suite, we made some procedural refinements or workflow refinements that made the procedures just go faster. We had a couple of steps that we asked our mappers to do, which took a couple of minutes but some of the physicians just

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didn't want to wait. They're standing table side, while we do some of these. And we've, in some cases, eliminated those steps, in some cases, shortened them by a factor of 10 or 100.

So these are -- they seem like little things, it's really technical, but this is just kind of the grinded out belt suspenders, figure out, listen to your customers, figure out what is keeping them from using us more often and push that out. Our team has just done an amazing job bringing these things out. And I think that's going to help incrementally and significantly in some centers and significantly in others.

Having ablation available in the U.S. is certainly going to help. Our Flutter trial is enrolling very well now. We have Steve McQuillan running that program. And we've got a solid number of centers up and our enrollment is going well. We do expect to have approval, be through the approval process for that right-sided flutter trial by the end of 2022 or early 2023, and that will certainly help.

William John Plovanic Canaccord Genuity Corp., Research Division - Analyst

Okay. And that actually was -- you kind of answered my final question, which was, is there any one thing or anything you feel that would really provide inflection for growth? So I think as we all sit here, we've all watched medical device companies develop over time. And usually, they kind of hit that point. And you really just it gets going, right? The top line just really starts moving. And I think I ask myself, what is that? Is that the ablation technology? Is it something else that can -- a step function increase?

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

I think AcQMap 8 with the automated region of interest finders and the other improvements has the potential. It's not proven out yet, has the potential as we roll that out and get people comfortable with it, to inflect that growth rate.

Operator

Our next question comes from Marie Thibault with BTIG.

Marie Yoko Thibault BTIG, LLC, Research Division - MD and Medical Technology and Digital Health Analyst

I wanted to use my first question here to try to understand the Q4 implied guide a bit better. As I sit here, it seems like procedure volumes should likely improve versus Q3 if we have a more normal profit environment. And it sounds like then you're expecting lower capital sales in Q4 than in Q3.

I'm curious why that would be, given that it feels like the environment for hospital access and some of these conversion conversations should be slightly more positive than it was in Q3. I don't know if Q3 was front-loaded. And you haven't seen quite that bolus yet in Q4, but maybe you could help us understand some of that.

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

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Sure. Thanks, Maria. And I'll use this as an opportunity also to correct my answer to Bill's question. We have 31 converted units in the field as of September 30, 17 in our direct business, and 14 with Biotronik. So to your point, you're correct. Our fourth quarter guidance does imply a flat to flat to down sequential revenue from Q3.

We did see significant capital purchases in the third quarter, largely through Biotronik. And if you recall, the second quarter we had a good amount of capital versus from Biotronik in Q1, effectively no capital revenue from them in Q2, a big step-up in Q3, and we are assuming that that does not recur here in Q4.

So the magnitude -- the third quarter was our biggest single AcQMap console revenue over the past 2 years. So we would expect capital, you're correct to be down sequentially. There could be an opportunity with respect to year-end budget flush at hospitals. As you know, the second and fourth quarter tend to be the largest periods of hospital CapEx spending.

We are not counting on that in our numbers, but the pool of convertible units is actually -- is quite significant, and our teams are very active in looking to convert these with significant interest. What we found is some of the administrative processes are very lengthy, and that has to do with a variety of factors.

So as we sit here today for planning purposes and for purposes of the guidance, we are assuming a step down in capital sales, and that is the primary driver, you're correct, in the fourth quarter guidance.

Marie Yoko Thibault BTIG, LLC, Research Division - MD and Medical Technology and Digital Health Analyst

That's well understood. Can you tell us how many systems were actually converted during the quarter? I recall the \$1.5 million revenue. How many systems does that translate to?

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

In the quarter about 11 systems were converted.

Marie Yoko Thibault BTIG, LLC, Research Division - MD and Medical Technology and Digital Health Analyst

That's helpful. Let me use my follow-up here on something kind of away from some of the commercial strategy. During the quarter, we saw a competitor get acquired by a large med tech company. I wanted to hear if that has an impact at all on sort of the transseptal crossing product portfolio? Are you having conversations? Or do you see any disruption or anything like that? Just curious for any underlying dynamics to that part of the portfolio?

Vincent J. Burgess Acutus Medical, Inc. - President, CEO & Director

So obviously, over the last couple of quarters, there have been a number of acquisitions. Boston Scientific acquired Farapulse on the pulse field ablation side of things for a very large number. Boston Scientific acquired Bayliss for a

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very large number. And I think just recently Integer acquired Oscor, which is a disposables manufacturer with a really nice number on it.

Let me touch on all 3 of those real quickly. Well, I'll touch on the first 2. Pulse field ablation is an area we have invested an extraordinary amount of time and energy. And we announced today that we commenced our CE Mark trial with a first site in Prague, Czech Republic.

That trial is extraordinarily important for the future of this company. This is a brand-new generator, PFA generator that we have designed from the wheels up, a purpose-built PFA generator that we've designed. We are pairing that with our mapping system, which is then paired with our delivery catheter, which, in our case, is going to be the single-shot point ablation catheter with force sensing on it.

To give you a sense of the level of interest, excitement, and the efficiency of these procedures, when you combine our mapping together with our catheter and our PFA generator, is in the first day at Prague today, we completed -- we've already completed 8 cases with the ninth ongoing. I believe all 8 so far and the ninth that's ongoing as we sit here today, also is utilizing our noncontact mapping catheter and system.

I mean those kinds of numbers are extraordinary, particularly with a new approach, new procedures, physicians, who are just getting up the learning curve today to be able to complete 9 cases, I think, is telling.

From a left heart access perspective, I believe in my bones, that we have a better product line today than Bayliss that Boston acquired for, I think, \$1.75 billion. We go head-to-head with Bayliss all the time, and we do very well. I don't expect that that will change under new ownership. I think we continue to do extremely well head-to-head there.

Having said that, crossing the septum as important as it is, a large number of physicians still do it kind of the old fashion way with a very long unprotected needle called the BRK needle. And I have found in my career that when you get sort of a behemoth coming into a space and bringing a focus on a new technology that it tends to expand the market and help kind of the rising tide rise all boats. And we think we'll be able to slipstream into that and parley a new and renewed focus on the importance of septal crossing safely and fast, quickly, as a result of this. So I don't see any negatives coming out of it. If anything, I see positive.

Operator

(Operator Instructions) Our next question comes from Amit Hazan with Goldman Sachs.

Amit Hazan Goldman Sachs Group, Inc., Research Division - Equity Analyst

I thought maybe just to come back to a few things. Just a clarification on a few things that have been covered. First on the '22 numbers. I think to your comment, David, on March, I think at a time, you had guided to about \$22 million to \$30 million in sales. I just want to make sure that that's the number you were roughly referencing in terms of saying you were one year behind.

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David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

Sure, Amit. So you're correct that that is the guidance that we had provided in March. We are not specifically providing any guidance here for 2022, but you are correct, and that is the guidance we had initially issued.

Amit Hazan Goldman Sachs Group, Inc., Research Division - Equity Analyst

Just on systems, as we think about the installed base next year, maybe a little bit of help, especially with the greenfield units and just kind of trends that you're seeing and what you would expect that installed base to grow to next year. So we know that there's the evaluation piece that will happen at a pace. But how should we think about the growth in the installed base next year for you?

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

Yes. It's a great question. And just to -- first, just an important point of clarification, those units that are under evaluation also are counted in our installed base because they are -- while they're not generating capital revenue, they are generating disposable revenue. And those evaluations ranged the gamut of time. Some of those are as short as 3 months and as long as 12. So those are reflected in our installed base, even though not all of the units are capital revenue generating.

So to put it in perspective, we would -- most of the repositioning effort that is netting against the gross increase in our installed base should be complete by the end of this year or into the first quarter of 2022. So you would probably expect more significant growth in our net installed base as we pace through 2022.

If you look at the kind of evolution of our installed base, we ended last year with 58. I think we had significant installations in 2020. We are at 76 as we sit here today. We will probably have some removal. So you look at the net increase that you might expect in 2021. We would expect a higher level of net installed growth next year, but aren't prepared to give a specific number.

So if you assume this year-end somewhere in the 20 to 25 net increase range, we would expect next year to be in excess of that. So 20 to 25 will probably include a net removal of 5 to 10 units or so. And we would expect the net removals to pace down next year.

Amit Hazan Goldman Sachs Group, Inc., Research Division - Equity Analyst

Yes, that's really helpful. Just maybe stick with you, David, on the last one for me. It's just on -- just given some of the changes in guidance, just cash burn considerations here, whether your expectations changed at all? And how if at all you think about kind of reallocating resources, just given the slower ramp than you might have expected earlier in the year.

David Harrison Roman Acutus Medical, Inc. - Senior VP & CFO

So what's interesting at this point in our ramp and the evolution of the commercial business, our operating expenses actually have a much more material impact on cash burn than anything else. So as I referenced in my prepared

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remarks, we are very actively looking across our investments, whether that's sales and marketing, R&D, critical corporate infrastructure, manufacturing, et-cetera, and looking at where do -- where is the highest priority and most effective use of those investments.

So we talked about operating expenses. They're bouncing around this kind of \$20.5 million to \$22-ish million range over the past several quarters. And while we're not giving operating expense guidance right now, we have kept that pretty flat the past several quarters while expanding the size of our commercial organization and investing in key research and development programs.

So we are looking for ways to sort of self-fund investments within the portfolio of our OpEx today. So as we think about the total cash burn profile, we are - I think on our last call, we had said we had cash through the middle of 2023 with the most recent raise. We would say the updated outlook with respect to sales still takes us through the first quarter of 2023.

Operator

This concludes today's conference call. Thank you for your participation. You may now disconnect. Everyone, have a wonderful day.

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