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 14, 2022

AZIYO BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39577**	**47-4790334**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904
(Address of principal executive offices) (Zip Code)

(240) 247-1170
(Registrant's telephone number, include area code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ 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 Symbols**	**Name of each exchange on which registered**
Class A Common Stock, $0.001 par value per share	AZYO	The Nasdaq Capital Market

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

Emerging growth company ☒

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

Item 2.02. Results of Operation and Financial Condition.

On November 14, 2022, Aziyo Biologics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022 and held a conference call to discuss those results. A copy of the Company's press release and a copy of the transcript of the conference call are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1 and Exhibit 99.2) 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 to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Aziyo Biologics, Inc., dated November 14, 2022
99.2	Transcript of conference call held on November 14, 2022
104	Cover Page Interactive Data File (formatted as 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 hereunto duly authorized.

AZIYO BIOLOGICS, INC.

Date: November 17, 2022

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer

Exhibit 99.1

Aziyo Biologics Reports Strong Third Quarter 2022 Revenue

Positive meeting with FDA provides clarity for CanGaroo® RM clearance

SILVER SPRING, Md., November 14, 2022 (GLOBE NEWSWIRE) – Aziyo Biologics, Inc. (Nasdaq: AZYO), a biologics company with a portfolio of regenerative products aimed at improving compatibility between medical devices and the patients they treat, today provided a business update and reported financial results for the third quarter ended September 30, 2022.

Recent Highlights

- Positive meeting with FDA provided clarity on path for first quarter 2023 clearance of the CanGaroo® RM Antibacterial Envelope
- Strong growth with net sales of $12.4 million, an 8% increase over third quarter of 2021
- Device compatibility business units (SimpliDerm® and CanGaroo®) achieved record sales with 18% year-over-year growth, further validating the Company's strategy
- Former Shire head of business development, David Colpman, added to Board of Directors
- Company raises lower end of FY22 revenue guidance range to $48 million to $50 million

"Aziyo's strong revenue performance reflects both our unique strategy and the team's exceptional efforts," said Dr. Randy Mills, Chief Executive Officer of Aziyo Biologics. "We are leveraging regenerative medicine to address the most frequent causes of implant procedure failure by improving compatibility between the medical devices and the patients they treat."

Dr. Mills added, "During the quarter, we made excellent progress towards clearance of the CanGaroo® RM Antibacterial Envelope, the only biomaterial envelope designed to mitigate complications in implantable pacemaker procedures. We are pleased to report that we held a positive meeting with the FDA to clarify outstanding items with our 510(k) submission. Based on Agency feedback, we believe we will be able to complete our responses to the FDA in time for an anticipated CanGaroo® RM marketing clearance in the first quarter of 2023."

"Looking ahead, our team is laser-focused on achieving further organic growth, while pursuing strategic relationships in areas where we believe such transactions would create significant shareholder value," said Dr. Mills. "I want to thank the entire Aziyo team for another great quarter."

Third Quarter 2022 Financial Results

Net sales for the third quarter of 2022 were $12.4 million, an increase of 8%, compared to the third quarter of 2021. Net sales of core products were $8.9 million in the third quarter of 2022, compared to $8.6 million for the third quarter of 2021, and net sales of non-core products were $3.4 million in the third quarter of 2022, compared to $2.9 million in the third quarter of 2021.

Gross profit for the third quarter of 2022 was $5.0 million and gross margin was 41%, as compared to $3.7 million and 32%, respectively, in the corresponding prior-year period. Gross margin, excluding intangible asset amortization (a measure not presented in accordance with U.S. generally accepted accounting principles ("GAAP")) was 48% for the third quarter of 2022, as compared to 40% in the third quarter of 2021. The increase in gross margin was primarily due to recent production efficiencies and improved inventory management.

Total operating expenses were $12.8 million for the third quarter of 2022, as compared to $10.7 million in the corresponding prior-year period, representing an increase of 20%. The increase was primarily due to $1.5 million in litigation expense associated with the 2021 recall of a single donor lot of the Company's FiberCel Viable Bone Matrix. This amount includes the difference between the current estimate of the Company's contingent liability and receivables from insurers and other parties. Additionally, there was a one-time $0.8 million charge related to the CEO transition.

Net loss was $9.9 million in the third quarter of 2022, as compared to $8.3 million in the corresponding period of the prior year. Net loss per share in the third quarter of 2022 was $0.73 per share, compared to a net loss of $0.81 per share in the third quarter of 2021. Aziyo's cash balance as of September 30, 2022, was $8.1 million.

Guidance for Full Year 2022

Aziyo updated its expectation that total net sales for the full year 2022 will be in the range of $48 million to $50 million. Excluding approximately $4.9 million of FiberCel sales in 2021, this range represents expected growth of 13% to 18%. This updated guidance compares favorably to the previous guidance range of $47 million to $50 million

Conference Call

Aziyo will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss its third quarter 2022 financial results, performance and vision for the future.

Individuals interested in listening to the conference call are required to register online. Participants are required to register at least 15 minutes before the start of the call. A live and archived webcast of the event and the accompanying presentation materials will be available on the "Investors" section of the Aziyo website at https://investors.aziyo.com/.

About Aziyo Biologics

Aziyo Biologics is a regenerative medicine company with a commercial portfolio of differentiated products focused on improving outcomes in patients undergoing a range of surgical procedures, primarily for implantable medical devices. Since its founding in 2015, the Company has created a portfolio of commercial-stage products used in cardiovascular, orthopedic, and reconstructive specialties. For more information, visit www.Aziyo.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. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements and information concerning the Company's anticipated financial performance; possible or assumed future results of operations, including descriptions of the Company's revenues, profitability, outlook, guidance for the full year 2022 and overall business strategy and expected success; expectations regarding the Company's operational position, opportunities and deliverables, goals, strategies, priorities and initiatives; and the timing of regulatory clearance and product launch. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, and other important factors that may cause actual results, performance or achievements to differ materially from those contemplated or implied in this press release, including, but not limited to, risks regarding the Company's products and its ability to enhance, expand and develop its products; the impact on the Company's business of the recall of a single lot of its FiberCel product and the discontinuation of its sales by its distribution partner; the Company's dependence on its commercial partners; the adverse impacts of COVID-19 or adverse changes in economic conditions; physician awareness of the distinctive characteristics, and acceptance by the medical community, of the Company's products; the ability to obtain regulatory approval or other marketing authorizations; and the Company's intellectual property rights, and other important factors can be found in the "Risk Factors" section of Aziyo's public filings with the Securities and Exchange Commission ("SEC"), including Aziyo's Annual Report on Form 10-K for the year ended December 31, 2021, as such factors may be updated from time to time in Aziyo's other filings with the SEC, including, Aziyo's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022 to be filed with the SEC, accessible on the SEC's website at www.sec.gov and the Investor Relations page of Aziyo's website at https://investors.aziyo.com. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement.

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AZIYO BIOLOGICS, INC.
CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

Assets	**September 30, 2022**	**December 31, 2021**
Current assets:		
Cash	$ 8,101	$ 30,428
Accounts receivable, net	7,159	5,996
Inventory	10,192	9,554
Receivables of FiberCel litigation costs	17,234	-
Prepaid expense and other assets	970	1,450
Total current assets	43,656	47,428
Property and equipment, net	1,359	1,200
Intangible assets, net	15,918	18,466
Other assets	89	76
Total assets	$ 61,022	$ 67,170
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,763	$ 10,424
Current portion of long-term debt and revenue interest obligation	7,750	10,809
Revolving line of credit	-	4,763
Contingent liability for FiberCel litigation	17,643	-
Other current liabilities	12	5
Total current liabilities	40,168	26,001
Long-term debt	20,000	10,410
Long-term revenue interest obligation	11,449	16,540
Deferred revenue and other long-term liabilities	86	698
Total liabilities	71,703	53,649
Stockholders' equity (deficit):		
Common stock	13	13
Additional paid-in capital	121,854	118,599
Accumulated deficit	(132,548)	(105,091)
Total stockholders' equity (deficit)	(10,681)	13,521
Total liabilities and stockholders' equity	$ 61,022	$ 67,170

AZIYO BIOLOGICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited, in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2022	**2021**	**2022**	**2021**
Net sales	$ 12,389	$ 11,485	$ 36,522	$ 36,529
Cost of goods sold	7,340	7,796	22,294	20,897
Gross profit	5,049	3,689	14,228	15,632
Operating expenses:				
Sales and marketing	4,915	4,783	15,139	14,285
General and administrative	4,487	3,516	13,223	10,501
Research and development	1,966	2,289	6,855	5,890
FiberCel litigation costs	1,474	77	1,908	226
Total operating expenses	12,842	10,665	37,125	30,902
Loss from operations	(7,793)	(6,976)	(22,897)	(15,270)
Interest expense	1,302	1,328	3,721	4,034
Other (income) expense, net	803	-	803	(3,579)
Loss before provision of income taxes	(9,898)	(8,304)	(27,421)	(15,725)
Provision for income taxes	12	12	36	43
Net loss	(9,910)	(8,316)	(27,457)	(15,768)
Accretion of Convertible Preferred Stock	-	-	-	-
Net loss attributable to common stockholders	(9,910)	(8,316)	(27,457)	(15,768)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.73)	$ (0.81)	$ (2.02)	$ (1.54)
Weighted average common shares outstanding - basic and diluted	13,660,555	10,235,350	13,618,580	10,229,974

Non-GAAP Financial Measures

This press release presents our gross margin, excluding intangible asset amortization. We calculate gross margin, excluding intangible asset amortization, as gross profit, excluding amortization expense relating to intangible assets we acquired in our acquisition of all of the commercial assets of CorMatrix Cardiovascular, Inc. in 2017, divided by net sales. Gross margin, excluding intangible asset amortization, is a supplemental measure of our performance, is not defined by or presented in accordance GAAP, has limitations as an analytical tool and should not be considered in isolation or as an alternative to our GAAP gross margin, gross profit or any other financial performance measure presented in accordance with GAAP. We present gross margin, excluding intangible asset amortization, because we believe that it provides meaningful supplemental information regarding our operating performance by removing the impact of amortization expense, which is not indicative of our overall operating performance. We believe this provides our management and investors with useful information to facilitate period-to-period comparisons of our operating results. Our management uses this metric in assessing the health of our business and our operating performance, and we believe investors' understanding of our operating performance is similarly enhanced by our presentation of this metric.

Although we use gross margin, excluding intangible asset amortization, as described above, this metric has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may use other measures to evaluate their performance, which could reduce the usefulness of this non-GAAP financial measure as a tool for comparison.

The following table presents a reconciliation of our gross margin, excluding intangible asset amortization, to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net sales	$ 12,389	$ 11,485	$ 36,522	$ 36,529
Gross profit	5,049	3,689	14,228	15,632
Intangible asset amortization expense	849	849	2,548	2,547
Gross profit, excluding intangible asset amortization	$ 5,898	$ 4,538	$ 16,776	$ 18,179
Gross margin	40.8%	32.1%	39.0%	42.8%
Gross margin percentage, excluding intangible asset amortization	47.6%	39.5%	45.9%	49.8%

Exhibit 99.2

Aziyo Biologics
Third Quarter 2022 Financial Results
November 14, 2022

Presenters
Matt Ferguson - Chief Financial Officer
Randal Mills - Co-Founder, President, CEO & Director
Kevin Rakin - Executive Chairman
Matt Steinberg - FINN Partners

Q&A Participants
Josh Jennings – Cowen
Simran - Piper Sandler
David Rescott – Truist Securities

Operator

Good day ladies and gentlemen and thank you for standing by. Welcome to the Aziyo Biologics third quarter 2022 earnings conference call. All lines have been placed on a listen only mode and the floor will be open for questions and comments, following the presentation. If you should require assistance throughout the conference, please press star zero to reach a live operator. Please be advised that today's conference is being recorded. I would now like to hand the conference call over to Matt Steinberg, FINN Partners. Sir, the floor is yours.

Matt Steinberg

Thank you, operator, and thank you all for participating in today's call. Earlier today, Aziyo released financial results for the quarter ended September 30th, 2022. A copy of the press release is available on the company's website. Before we begin, I'd like to remind you that management will make statements during this call, that include forward looking statements within the meaning of Federal Securities laws, which are pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. And the statements contained in this call that do not relate to matters of historical fact or relate to expectations or predictions of future events, results or performance or forward looking statements.

All forward looking statements including, without limitation, those relating to our operating trends, and future financial performance are based upon our current estimates, and various assumptions. These statements involve material risks and uncertainties that could cause actual results or events to materially differ from those anticipated or implied by these forward looking statements. Accordingly, you should not place undue reliance on the statements.

For list and description of the risks and uncertainties associated with our business, please refer to the risk factors section of our of our public filings with the SEC, including Aziyo's annual report on form 10k for the year ended December 31st, 2021. And such factors may be updated from time to time and Aziyo's other filings with the SEC, including the CEOs quarterly report on form 10 Q for the quarterly period ended September 30th, 2022, to be filed with the SEC accessible on the SEC's website, www.sec.gov. The conference call contains time sensitive information and is accurate only as of the live broadcast today, November 14th, 2022. Aziyo Biologics claims any intention or obligation except as required by law to update or revise a financial projections or forward looking statements, whether because of new information, future events or otherwise.

Also, during this presentation, we refer to gross margin excluding intangible asset amortization, which is a non-GAAP financial measure. A reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure is available in the company's earnings release for the third fiscal quarter ended September 30th, 2022, which is accessible on the SEC's website and posted on the investor page on Aziyo's website at www.aziyo.com. And with that, I will turn the call over to Aziyo's CEO, Randy mills.

Randal Mills

Thank you very much, I am really excited to be with everyone today, I've now completed my first 100 days or so as the new CEO of Aziyo. Of course, while I'm new to the role of CEO, I am not new to the company, having been a co-founder of the company. During the first 100 days, though I'm really pleased and proud of the team for two things. One is creating a clarity of vision, which I think is exceptional and unique, two, is the execution of that vision by the team. And so, I'm going to talk about those two things in my remarks today.

Going back into my career as one time CEO of Osiris Therapeutics for 10 years, took the company public as the President and CEO of the California Institute of Regenerative Medicine and a host of other physicians, I've literally been the poster child of regenerative medicine. And so often we framed the argument as regenerative medicine versus medical devices, and wouldn't you rather have a regenerative medicine solution in your body versus a foreign medical device? But the reality is, medical devices worked really, really well. This is data for pacemakers, but it holds true for any class 2 or class 3 medical device. When you look at primary failures, that is how often the device itself fails, it is very rare with pacemakers. It comes in at only 0.13%.

But when you look at how well the device works for the patient, it's a completely different story. And so procedure failures, that is, how often the implantation in this case, again of a pacemaker, how often that procedure is successful, 6% of the time those procedures will fail. And so, what's the difference, what's going on here between primary device failure of 0.13%, and a procedure failure of 6%? Well inside [PH} this device host interface, where these failures are coming from. And if you're a patient, that's all that matters, it doesn't matter whether or not the device failed because of the device, or whether or not it's failed because you had an infection or hematoma, or erosion or any number of other device host complications that can arise. Our bodies simply don't like foreign objects being implanted in them.

Same thing would happen if you got a splinter in your finger, your body does what it can to either eject it or wall it off. And so that's as a company, the field in which we're going after this concept of device compatibility, and where we think we have the biggest opportunity for both top line and bottom line growth.

Today, we have built a company around this premise at Aziyo. We have four fully integrated business units, all wrapped around a very sophisticated research develop and in development and manufacturing team that's producing about $50 million in revenue, with a significant growth rate going on. This is a commercial stage business with diversified portfolio of revenue, and a late-stage pipeline behind that. And we think that represents a tremendous opportunity for future growth. Looking at what the company has accomplished this quarter, I'm going to start off with what perhaps is the most important thing. And that is, I'm going to provide some comments regarding a meeting that we recently held with FDA on the path to clearance for CanGaroo RM, which is our antibiotic eluting envelope.

Dr. Williams, our Chief Scientific Officer, has recently just joined the company. And obviously, I just joined the company, took over the responsibility for getting this product approved, and wanted to hear directly from the Food and Drug Administration on what items specifically were outstanding before approval could be granted. And so we recently held a meeting with FDA. And we got very precise clarity around what FDA wanted to see from us, which really all centered around a device stability protocol going forward, so for improving the expiration dating on the product. More importantly, what the FDA didn't want was any additional data around product performance, safety, or efficacy or anything of the like. And so, we think we're in very good shape right now, we have a very clear path.

We know what FDA want, and we think we're in a good position to provide that information to FDA in time for a first quarter clearance of this product. And so, we're super excited about that. Behind that, we've got a team that's executing, so strong growth, with net sales of $12.4 million, which is an overall 8% increase. But when you look at our high growth segments of our business, which is our SimpliDerm, and our CanGaroo RM, they have their highest quarter in company history with 18% year over year growth, which we think is further validating this strategy, that device compatibility is actually a really significant unmet medical need going forward. We added former Shire Head Of Business Development, David Colpman to our Board of Directors.

Importantly, David's got a lot of strategic transaction experience as obviously as the head of business development for Shire. And that's important for us as we continue to contemplate certain partnerships and transactions moving forward. Lastly, the company's raised the lower end of guidance from $47 to $50 million, tighten that a little bit up to $48 to $50 million. And so this has really been a great story of execution, in this quarter. Matt's gonna go into it more, but it's not just at the top line, we see control of operating expense, we see significant improvements in lowering cost of goods, and improving gross margin.

And we think on these fronts we really just begun. Just to familiarize you with our four different business units, really the first time we've talked about the company in this respect of four different business units. The first stuff that we have is our Women's Health Business Unit. Here, again, we don't make the primary medical device, we make the device that makes the breast implant possible. And so, these are primarily used in procedures where a woman has received a diagnosis of some type of breast cancer, had a therapeutic mastectomy as a result, and then needs to have the breast reconstructed. And the product we make SimpliDerm is used to contain the expander after it's been put in place, as part of that reconstruction procedure. What do we like about this market? Well, one, we have a great product.

The second centers around the market dynamics and the opportunity that exists here, the market leader in this space was recently acquired by a very large traditional pharmaceutical company. And they have stopped paying sales commissions on acellularized [PH] dermis, and that has created a pretty significant void in the market, as you can imagine. And so, our strategy here is really straightforward. We are running after and capturing market share in that market space, by increasing the number of independent reps that we have, and also by the distributors that we are working with, to speed our penetration into this market. We also have significant efforts going on here to lower our cost of goods with certain process improvements that we put in place, going forward. So we're very excited and very well positioned in the women's health market.

The next up is Cardiac Device Protection. Here's where we have our marquee CanGaroo franchise. This is a pouch that goes around pacemakers and electronic defibrillators. It's about a $600 million market opportunity for us. Again, though, we really like the market dynamics here. So there's only four major players in the pacemaker market in the United States, the market leader here has established the need for an envelope because they have one, we happen to have the only other envelope on the market. And so, we really like where that positions Aziyo and the CanGaroo franchise, our strategy here also very straightforward. Get CanGaroo RM approved and launch that product.

It's an antibiotic eluding version of the CanGaroo product, which will prevent bacterial colonization and further infection post-operatively. We think once we have that clearance in place, we are in a prime position for a partnership, a major global partnership, for this product in the pacemaker and CIED space. From there, we're going to launch products into the sleep apnea and neurostim space. So we see tremendous growth opportunity and up front opportunity with our cardiac device protection business.

Turning to cardiovascular, the same actual material and technology that we use in our CanGaroo business, which is this porcine derived extracellular matrix or ECM, also has tremendous value in the cardiovascular space. And so here, these products, ProxiCor and VasCure and Tyke, are used to close open cardiac procedures. So to close the pericardium following open heart surgery, or to close a major vessel following a procedure, such as an endarterectomy, where you’re opening the carotid or femoral artery, and then often used in children undergoing—septal defects in the child. This is a great business for us, it's more of a mature business. So it's not a real top line growing business, but it has very nice gross margins and contributes significantly to the company.

And then lastly, I'll round this out by talking about our orthobiologics business, this was a little different in how we approach the sale. So unlike the others, this is more of a B2B play. And what we do here, we've literally created the space of orthobiologics. And what we do here is we're able to go to other orthopedic or spine companies who perhaps don't have the same level of sophistication with biologics as we do, and we're able to provide them a turnkey solution to not just develop them a proprietary product, but also to manufacture and supply that product going forward.

It's a relatively unencumbered space for us. And so, here we see pretty reasonable top line growth, but we see fantastic growth at the bottom line. In fact, we're targeting a 2X growth in operating income from this unit in 2023, largely driven by process improvements, aimed at lowering our cost of goods. So that's just to give you an idea of our current business. Matt's gonna provide some color around our financial update, Matt Ferguson?

Matt Ferguson

Okay. Thanks, Randy. So from a financial perspective, in addition to what Randy talked about from the revenue perspective, with the top line growth that we saw, we also saw a good performance in terms of gross margins, where on a GAAP basis, we turned in 41%, gross margin, that's up nine points from the previous year in Q3 when it was 32%.

And then on a non-GAAP basis, which is probably more indicative of the real operating performance, we were at 48%. And that really relates to process improvements that we've been making and will continue to make, as well as better inventory management. And that's up about eight points from the prior year. From an opportunity operating expense point of view, we were at $12.8 million for the quarter. That's up about $2.1 million from the prior year, third quarter. But that includes a couple of items that were somewhat anomalous, we had the CEO transition, and there was about $800,000 of expense related to that process that we went through, that was taken in the third quarter.

And then importantly, we had about a million and a half of expense related to FiberCel litigation. And for those of you who have been following the company, you know that we had a recall of a single donor lot of FiberCel product back in the second quarter of 2021. And we've had quite a few lawsuits that resulted from that. But we are now at the point where we've actually settled a pretty large number of those, we've settled about 24 of those claims and lawsuits, just recently, and that has given us enough information to, for the first time, estimate the overall liability associated with that pool of litigation.

And we've done that in the current quarter. And we have also recognized the corresponding receivables associated with the insurance that we have that covers us for that. And so, the net difference between the overall liability and the insurance receivables that we've recognized, is about $1.5 million, which includes the expense that we took during the quarter. And we still have the opportunity actually, to go after additional recovery in terms of receivables and insurance coverage there. So we actually are quite pleased with the situation there. It's good to get this very much behind us, and we will continue to work to settle additional cases. But we now have a clearer picture in terms of what the overall cost was. And we really feel quite confident that we can manage that effectively, going forward.

The only other points I'll touch on from the list here, we ended the quarter with $8.1 million in cash. And then we did increase the bottom end of our revenue guidance range for the full year. The new guidance range is $48 to $50 million. That compares favorably to the $47 to $50 million range, which we set at the beginning of 2022.

And with that, I will hand it back to Randy, before we take questions.

Randal Mills

Great. Thank you, Matt. I'll just finish up by trying to provide some clarity around our priorities and potential catalysts moving forward, I like clarity, and so does the organization. So first and foremost is CanGaroo RM clearance from the FDA, our teams are working. As they said, we held a very positive meeting with the FDA, we think we have the clarity we need to provide FDA with the information they have requested. And if all goes well, we would expect clearance of this product in the first quarter coming up. Second, is we are evaluating a number of global partnership opportunities for our CanGaroo pacemaker franchise. The purpose here is to accelerate the growth of this franchise, particularly in the pacemaker market globally, and in a cost conscious manner.

Third, is improving our cash flow out of our orthobiologics business unit. As mentioned, we think we have the opportunity to double our operating income, out of this business unit. We've already implemented certain process improvements that have resulted in significant improvements in gross margin. We think that's just the beginning. So we're working on that one. Fourth, is expand our commercial footprint to capture a SimpliDerm market share from the market leader. We have a great product. The surgeons love our product and we think the market leader has taken their eye off the ball, and that provides us a unique opportunity to go after it. And so we're doing that both with independent reps, as well as selective distributorships that we're adding.

Fifth, is build out the rest of our device compatibility platform, or CanGaroo and the like, in the sleep apnea space neurostimulator, and then, ultimately leveraging our CanGaroo RM technology into our SimpliDerm franchise where postoperative infection is actually a bigger problem, something around 9% to 11%. And then lastly, contemplating a number of different strategic transactions and partnerships. So we've received interest for partnerships or other types of transactions across all four of our business units. We think through these partnerships, we have the opportunity to add cash, shareholder value, and to add significant product growth in the near term, as well as the long term. However, I want to be really clear here, we will be very selective about any transaction that we consider executing.

I hope that provides you with a good sense of what this company has done during the third quarter, and what it is that we are aiming to do going forward both from a strategy standpoint, as well as from a very specific priority standpoint. I want to end by thanking our employees, the team of Aziyo has been fantastic, welcoming me into the team in the first 100 days, and for just keeping their eye on the ball, and executing beautifully for this period. Team, thank you so much. Your efforts are very sincerely appreciated. So with that, I will conclude my comments and turn the call over to the operator, for questions.

Operator

Thank you, ladies and gentlemen, the floor is now open for questions. If you do have a question, please press star one on your telephone keypad at this time. If you're using a speakerphone, we ask that while posing your question, you just pick up your handset to provide favorable sound quality. Once again, ladies and gentlemen, if you do have a question or comment, please press star one on your telephone keypad, at this time. Please hold as we poll for questions.

And we'll take our first question from Josh Jennings, from Cowen. Please go ahead, Josh.

Josh Jennings

Hi, good evening. Thanks a lot for taking the questions and appreciate the thorough update. Wanted to just send us two questions, one, just on the device compatibility portfolio and just clinical data accrual. Any datasets that we should have on our radar in the next 12 months or so that will enhance the marketing of SimpliDerm and CanGaroo? Clearly CanGaroo RM approval is going to be a big a big deal for that franchise. But just wanted to think about any clinical datasets that are on the common? And then lastly, just in terms of building out the device compatibility portfolio, sleep apnea, nerve stimulators, SimpliDerm RM, any just initial steps or any kind of I guess, guideposts just in terms of the development requirements, or the burden that you see for your development team? And I mean, seems like it could be straightforward pathways for each of the categories you laid out, but just wanted to get a better sense of what those development trajectories could look like. Thanks.

Matt Ferguson

Thank you. So I'll try to categorize the two questions. First, is capturing clinical data around our device compatibility, because we actually have two different studies going on in device compatibility. Our new Chief Scientific Officer, Dr. Michelle Williams has come in and is now overseeing those programs and medical affairs. I am not sure exactly on the timing for when we're going to be releasing data on that. But I know both of those trials, once completed, will be something that is suitable for publication in a high quality journal. And I'll get back to you more specifically, with expectation timing around that.

I certainly do appreciate the question. The second is building up and building out the device compatibility franchise, here, what we're looking at doing, we think the pacemaker indications here and probably with a with a pretty significant global partnership, our next stop is, is taking the product and franchise into the neurostim business. And the reason for that centers around, we currently actually have approval for that space, as well as for the implantable defibrillator space. And so, those two would be the next logical stop for us. Right behind that, though, is sleep apnea. And so, we were recently just at the EMT conference in Philadelphia, held great meetings there around the clinical need, which we think in this indication is quite significant.

And so we really like the sleep apnea space, particularly—and we're talking about implantable stimulators in the sleep apnea space, obviously, but particularly for device differentiation in a market there, where they're just getting into the meaty part of this market, being able to partner and create significant separation from the others we think is a real opportunity. Lastly, we mentioned and you as well, this concept of, of expanding our RM platform and our RM technology into other products. And for us, a very obvious and real one is in our SimpliDerm franchise, we're looking at in the rest of the rest of the world is looking at post operative infection rates in the 9% to 11% range, which is just wholly unacceptable.

We've been active out in the plastic surgeon reconstructive breast surgery community, talking and doing surveys and the like. And we've found about an 80% strong interest or demand in a version of SimpliDerm, combined with our CanGaroo RM technology, we think the work we've done with RM on the CanGaroo side lends itself to moving into that franchise more easily. With that said, this, from a regulatory standpoint, is through a PMA process, but it would not be through the just generic breast reconstruction pathway, it would be specifically around an indication for prevention of infection. So I hope that provided you some color around those two questions.

Josh Jennings

Absolutely. Thanks so much.

Operator

Thank you, and we'll take our next question from Matthew O'Brien, from Piper Sandler. Please go ahead, Matthew.

Simran

Hi, this is Simran on for Matt, thank you for taking the questions. So maybe just starting off on CanGaroo RM, it sounds like we can expect the product to be commercial by the end of Q1 next year. So I guess, any additional color on the launch strategy? How should we think about initial commercial revenues? And what do we assume from stocking as well?

Randal Mills

Sure. So right now, what we're anticipating, and this was based on conversations we held with the FDA, would be a clearance in the first quarter. An actual launch strategy would really, and really will be largely predicated on any particular transaction that we would consummate in the pacemaker space. We currently have a sales organization in this space, doing a really good job. But we think the opportunity exists for this product to really explode onto the market, if our sales agents are put in the position of detailing the device more as a medical science liaison, and having the actual individual cases covered by a major device company with a pacemaker, where they would already be in the case.

And so at this point, it would be probably premature to detail more specifics about the launch other than we would expect that launch to be done in coordination, with a major device company and therefore we would expect uptake to be to be pretty significant, if not transformational for the organization.

Simran

A quick follow up there? Is it safe to assume that we won't see the launch of this product until the execution of an additional commercial partnership? Or do you think you can leverage your existing commercial partners to kind of get this product going, after approval?

Randal Mills

Well, we have a great commercial partner right now in Boston Scientific, for our current CanGaroo products, and we work with -- we work with Boston Scientific every day on the distribution of the non-antibiotic version of this product. Under that relationship, there is tremendous opportunity for us, to improve the mechanics of our working relationship, which would make the sale and distribution of products, particularly into the US much, much easier and much more competitive with other products, which might enjoy a more of a bundling strategy.

And so, I would say right now, we have the ability to launch the product on our own, but I would expect that we would be more likely than not to have a more robust partnership in place, prior to the launch of CanGaroo RM.

Simran

And if I could just squeeze one quick one in here on the guidance. So I think by my math, the guidance range that was raised on the low end implies a sequential step up of about a percent at the midpoint. So firstly, is that bump solely due to this performance in the OEM business? Or is something else helping there? And how are you thinking about contributions from SimpliDerm and CanGaroo in the quarter?

Matt Ferguson

Yes, Simran, this is Matt, I can speak to that, , it really, it has to do with being three quarters of the way through the year and having performed well during the year to date, period, and, you know, having a good sense of where we'll be by year end. The contributors so far really have been pretty much across the board. But we've called out both this quarter and last quarter that the fastest growing areas were CanGaroo and the SimpliDerm product lines. And so, you know, they are driving the growth on a year over year basis, and no sequential basis. And we would expect that probably will be the driver going forward into Q4 and beyond that level as well. We've also seen good results in, as you said, the OEM business, the orthobiologics business, and, and that will be a contributor to but we really do see the device compatibility areas that have CanGaroo and SimpliDerm being the real drivers of growth, going forward.

Simran

Okay. Perfect. Thank you, guys.

Matt Ferguson

Thank you.

Operator

As a reminder, that star one if you do have a question or comment, and we'll take our next question from David Rescott from Truist Securities, please go ahead, David.

David Rescott

Hey, guys, thanks for taking the question. I just want to first start on the updated timing for the CanGaroo launch, I guess. Can you just provide some more information around what led to the updated timing there? I guess what the specific steps that you are undertaking to get that out by Q1? And then what the visibility into the approval timing is from an FDA standpoint?

Randal Mills

Sure, David, I'll do my best to fill this in with as much background as I can. First of all, I participated in this call, personally, myself, because I wanted to be able to hear firsthand where we were going. I do need to provide some background on why I did that. And it's not because I don't have trust or confidence in the team. Earlier this year, I had brought in Dr. Michelle Williams as our Chief Scientific Officer. And she took over running not only product development, R&D, but regulatory, and medical affairs, as well, and has an outstanding background, I've worked with her for the last 18 years.

What probably is not known is that our Head of Product Development at that time, and the one that had prepared the submission unexpectedly died. And it didn't leave us uncovered, he had built a great team, and the addition of Michelle was obviously very fortunate in timing. But it did leave us with a direct firsthand knowledge and understanding of the approval process, and what was going on there. And so because of that, we wanted to make sure we were providing FDA exactly what they wanted. What we didn't want to do, David was, we didn't want to provide them information without really knowing specifically their needs, and for no good reason end up with an NSC.

Because we think the product obviously, has merits that warrant its clearance. And so that's why we held the meeting. That's one of the reasons that we ended up with this gap, because we actually paused the submission of materials, until we held this meeting. As I said in the call, really the only outstanding items that we talked about with FDA, and not only did we have specific questions, but we also asked them very open ended, Is there anything else that you know that we're missing here, and they responded that there was not. Really the question’s centered around stability studies moving forward, for the extension of product life expiry, and basically the shelf life of the product. Because this is a product that has both a drug and a device component, it is being run jointly between the Center for Device and the Center for Drugs.

And that sometimes can create some confusion between the two members of the agency. And so we were very gratified to find out that really, what their questions were, that we actually had answers for the vast majority of them and that more importantly, we didn't have to generate any new safety or efficacy data on the product. With regards to the timeline moving forward, as I said, we're finishing up our response to them. And we think we will be able to get that in, as I said, enabling them sufficient amount of time to be able to give us a decision and hopefully a clearance in the first quarter.

David Rescott

Okay, that's helpful. And then maybe one for Matt, with this the litigation, I guess I'm FiberCel and the P&L, I guess, a couple of kind of clarification questions. Is that something that is, you know, recurring on a quarterly basis? Or is that just limited to Q3? And then, I know there are some moving pieces around kind of just the recent raise, some of the liabilities and receivables that are recorded on the balance sheet just around this. So just wondering what we should be thinking about from like a true kind of capital position? And how you're thinking about that position, as well as the investment priorities going forward? I think just in the balance sheet, there's about $8 million or so left in cash, I was trying to understand what that true kind of balance sheet position is, from a cash perspective. Thank you.

Matt Ferguson

Sure, David. So on the FiberCel litigation categories, it is a little bit of a complex area, but something that we've been working really hard on, over the course of the last year plus. And, you know, we've known that there was some level of exposure there, but it was really hard to quantify it until we actually got face to face with plaintiffs and their counsels and really understood what the details of the various claims were. And so, we now have done that in a large number of the cases. And that's what has allowed us it's given us a lot of detailed information, and some actual precedents in terms of the cases having been settled.

And so we have the liability on our balance sheet, which is about $17.5 million dollars $17.6 million, I think it's the total estimate of the liability. And then we have insurance proceeds that basically cover that with some potential to recover even more, from insurance for the small delta between those two. So those estimates, particularly the estimate of the liability is something that we will adjust as we continue to get more information. So for instance, as we continue to settle more cases, and as time goes by, and we have more information.

And -- but right now, what we have is based on a lot of good data, and we think it's a good estimate. So hopefully, that helps there in terms of understanding what it is. So back to your original question, I would not see that as something that is a recurring expense, the amount that we showed in Q3, there could be some adjustments of the estimates on the balance sheet from time to time, but by and large, we really feel like those are covered by insurance that we that we have.

So I think that was the main question in this in terms of the overall balance sheet, you know, we have the cash on hand, and we feel like we're in a good position between the various potential sources of cash that we have going forward, whether it's from the credit facilities that we have in place, or support from our current shareholders, or the strategic transactions that we have alluded to, and that we are working on very hard and feel like could actually be very impactful in terms of contributions, to cash on our balance sheet.

David Rescott

Great, thank you.

Operator

Thank you. And that was our last question. Ladies and gentlemen, this does conclude today's teleconference. We thank you for your participation. You may disconnect your lines at this time, and have a great day.