Elutia Reports 26% Year-Over-Year Sales Growth of Proprietary Products and Strengthened Balance Sheet in Third Quarter 2023 Financial Results

November 13, 2023

- Anticipate 510(k) filing for transformational Drug-Eluting Biomatrix CanGarooRM in Fourth Quarter

SILVER SPRING, Md., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia"), a company pioneering drug-eluting biomatrix products, today provided a business update and financial results for the third quarter ended September 30, 2023.

Business Highlights:

- Successfully completed transformation to Elutia, establishing a high growth company dedicated to developing and marketing propriety drug eluting biomatrices.
- Achieved a significant 44% year-over-year increase in SimpliDerm® net sales and an 11% year-over-year growth in CanGaroo® net sales.
- Divested Orthobiologics business unit for initial gross proceeds of $15 million, and up to $35.0 million in total proceeds.
- Closed private placement financing, securing initial gross proceeds of approximately $10.5 million, and up to $26.2 million in total proceeds.
- Completed validation of an accelerated in-vitro elution assay for CanGarooRM and held productive pre-submission meeting with FDA, paving the way for 510(k) submission in 4Q23.
- Published case report in peer-reviewed journal *Heart Rhythm Case Reports* highlighting the benefits of bioenvelopes for reoperative procedures.

"This quarter was transformational and I am pleased that Elutia is off to a great start," said Dr. Randy Mills, President and Chief Executive Officer of Elutia. "Our commercial teams delivered outstanding results, growing our proprietary product lines, CanGaroo and SimpliDerm, by 26% year-over-year. We were particularly excited to see SimpliDerm sales accelerate during the quarter through our partnership with Sientra."

"Looking ahead, we anticipate submitting our FDA 510(k) filing for CanGarooRM, the most advanced drug-eluting biomatrix product in our pipeline, before the end of 2023. Having completed the necessary validation studies, we recently held a productive pre-submission meeting with the FDA, setting a positive trajectory ahead of a decision in the first half of 2024. We believe CanGarooRM represents our greatest near-term opportunity as we seek to capture a significant share of the CIED envelope market estimated at $600 million," remarked Dr. Mills.

Dr. Mills concluded by commenting on recent financial moves, stating, "Lastly, we completed a private placement of stock and warrants and closed the divestiture of our Orthobiologics business unit. These transactions immediately fortify our balance sheet and have the potential to bring in a total of $60 million, which we'll use to drive topline growth, develop best-in-class products, and retire a portion of our outstanding debt. Having accomplished these critical steps, we believe we are poised to deliver substantial value for our shareholders."

CanGarooRM Update

In the third quarter, notable progress was made in advancing the 510(k) filing for CanGarooRM, focused on addressing completely the issues raised in the not-substantially equivalent letter we received in March. Our proactive approach included a presubmission meeting with the FDA to collaboratively chart the path forward. The FDA's primary request, the establishment of an accelerated drug release test method, has been successfully developed and validated. This method, simulating drug release within 48 hours, meets the requirement of over 80% drug release for quality control and stability testing. As a result, we anticipate filing a fully responsive resubmission by year-end.

The market for drug-eluting cardiac device envelopes is estimated at over $600 million annually. As only the second entrant and the sole product offering the combined benefits of a biological envelope and potent antibiotics, rifampin and minocycline, we believe CanGarooRM is well-positioned to compete effectively in this space.

Third Quarter 2023 Financial Results

Net sales for the third quarter of 2023 were $6.1 million, compared to $5.8 million in the third quarter of 2022. Net sales of both SimpliDerm and CanGaroo performed well, growing 44% and 11%, respectively, versus the third quarter of 2022. Net sales growth was partially offset by a decline from the Cardiovascular business unit due to the commencement of the Company's distribution agreement with LeMaitre Vascular, which resulted in increased sales volume but at distributor transfer pricing rather than the previous end-user pricing.

Gross profit for the third quarter of 2023 was $2.8 million and gross margin was 46.4%, as compared to $2.9 million and 50.2%, 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 60.2% for the third quarter of 2023, as compared to 64.8% in the third quarter of 2022. The decline in

gross margin was primarily related to the Cardiovascular business which declined due to the previously mentioned transition to distributor sales versus direct sales in the prior-year period.

Total operating expenses were $10.2 million for the third quarter of 2023, down 14% as compared to $11.9 million in the corresponding prior-year period.

Net loss from continuing operations was $8.5 million in the third quarter of 2023, down 23% as compared to $11.0 million in the third quarter of 2022. Net loss from continuing operations per share in the third quarter of 2023 was $0.50 per share, as compared to a loss of $0.81 per share in the third quarter of 2022.

Net loss from discontinued operations was $1.2 million in the third quarter of 2023, as compared to net income of $1.1 million in the corresponding prior-year period. Net loss from discontinued operations per share in the third quarter of 2023 was $0.07 per share, as compared to net income of $0.08 per share in the third quarter of 2022.

Elutia's cash balance as of September 30, 2023, was $14.5 million, which includes the initial gross proceeds from the private placement completed in September 2023 of approximately $10.5 million but does not include proceeds from the Orthobiologics business unit divestiture that closed in November 2023.

Conference Call

Elutia will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss its third quarter 2023 financial results and performance.

Individuals interested in listening to the conference call are required to register online. Participants are recommended 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 Elutia website at investors.elutia.com.

About Elutia

Elutia develops and commercializes biologic products to improve compatibility between medical devices and the patients who need them. With a growing population in need of implantable technologies, Elutia's mission is humanizing medicine so patients can thrive without compromise. For more information, visit www.Elutia.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. Forward-looking statements can be identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise" or similar references to future periods. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including any statements and information concerning our expectations for our drug-eluting biomatrix technology aimed at improving surgical outcomes, any milestones or projections for our CanGaroo® and SimpliDerm® products and the outcome of our FDA 510(k) submission for our CanGarooRM product. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect our 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 associated with shifting focus to our drug-eluting biomatrix solutions in the cardiovascular and breast reconstruction areas and away from our now-divested Orthobiologics business; risks regarding the ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra; our inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; our ability to continue as a going concern; our ability to successfully execute or achieve expected benefits from the divestiture of our Orthobiologics business; our products and our ability to enhance, expand, develop and commercialize our product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; consequences of our recall of a single lot of one of our viable bone matrix products and market withdrawal of all of our viable bone matrix products; our dependence on our commercial partners; the impact of the bankruptcy of Surgalign Holdings, Inc., a significant customer of the Company, on our future revenues; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; the ability to obtain regulatory approval or other marketing authorizations; the possibility of adverse determinations in our FDA 510(k) submission process; future revenues of the disposed-of Orthobiologics business and its impact on "earn out" provisions in the related acquisition agreement; the possibility that our stock will be delisted from the Nasdaq Capital Market; and our intellectual property rights, and other important factors which can be found in the "Risk Factors" section of Elutia's public filings with the Securities and Exchange Commission ("SEC"), including Elutia's Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in Elutia's other filings with the SEC, including Elutia's Quarterly Reports on Form 10-Q, accessible on the SEC's website at www.sec.gov and the Investor Relations page of Elutia's website at https://investors.elutia.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. Any forward-looking statement made by Elutia in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, Elutia expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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ELUTIA INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In Thousands, Except for Share and Per Share Data)

(UNAUDITED)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 14,517	$ 16,989
Accounts receivable, net of credit loss reserve of $652 and $87, respectively	2,883	3,774
Inventory	6,503	4,240
Receivables of FiberCel litigation costs	7,452	13,813
Prepaid expenses and other current assets	452	2,387
Current assets of discontinued operations	7,320	9,496
Total current assets	39,127	50,699
Property and equipment, net	175	245
Intangible assets, net	12,520	15,069
Operating lease right-of-use assets and other	155	320
Noncurrent assets of discontinued operations	2,603	2,508
Total assets	**$ 54,580**	**$ 68,841**
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,962	$ 1,374
Accrued expenses and other current liabilities	10,723	8,830
Payables to tissue suppliers	707	900
Current portion of revenue interest obligation	11,053	8,990
Contingent liability for FiberCel litigation	15,702	17,360
Current operating lease liabilities	399	232
Current liabilities of discontinued operations	3,190	4,929
Total current liabilities	44,736	42,615
Long-term debt	25,278	24,260
Long-term revenue interest obligation	5,471	5,916
Warrants and other long-term liabilities	7,983	127
Noncurrent liabilities of discontinued operations	585	956
Total liabilities	84,053	73,874
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Class A Common stock, $0.001 par value, 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022, and 18,852,930 and 11,823,445 shares issued and outstanding, as of September 30, 2023 and December 31, 2022, respectively	19	12
Class B Common stock, $0.001 par value, 20,000,000 shares authorized, as of September 30, 2023 and December 31, 2022 and 4,313,406 issued and outstanding as of September 30, 2023 and December 31, 2022	4	4
Additional paid-in capital	136,834	132,939
Accumulated deficit	(166,330)	(137,988)
Total stockholders' deficit	(29,473)	(5,033)
Total liabilities and stockholders' deficit	**$ 54,580**	**$ 68,841**

ELUTIA INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Data)

(UNAUDITED)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2023	2022	2023	2022
Net sales	$ 6,127	$ 5,849	$ 18,870	$ 17,262
Cost of goods sold	3,286	2,910	9,943	8,689
Gross profit	2,841	2,939	8,927	8,573
Sales and marketing	2,802	4,379	10,514	13,672
General and administrative	2,757	4,330	10,137	12,788
Research and development	557	1,723	3,016	5,867
FiberCel litigation costs, net	4,096	1,474	7,278	1,908
Total operating expenses	10,212	11,906	30,945	34,235
Loss from operations	(7,371)	(8,967)	(22,018)	(25,662)
Interest expense	1,448	1,247	4,285	3,666
Other income, net	(312)	803	(312)	803
Loss before provision for income taxes	(8,507)	(11,017)	(25,991)	(30,131)
Income tax expense	12	12	36	36
Net loss from continuing operations	(8,519)	(11,029)	(26,027)	(30,167)
Discontinued operations	(1,228)	1,119	(2,315)	2,710
Net loss	(9,747)	$ (9,910)	(28,342)	$ (27,457)
Net loss from continuing operations per share - basic and diluted	$ (0.50)	$ (0.81)	$ (1.58)	$ (2.22)
Net loss from discontinued operations per share - basic and diluted	$ (0.07)	$ 0.08	$ (0.14)	$ 0.20
Weighted average common shares outstanding - basic and diluted	17,017,610	13,660,555	16,464,262	13,618,580

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.

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.

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. 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,	
	2023	2022	2023	2022
Net sales	$ 6,127	$ 5,849	$ 18,870	$ 17,262
Cost of goods sold	3,286	2,910	9,943	8,689
Gross profit	2,841	2,939	8,927	8,573
Intangible asset amortization expense	849	849	2,547	2,547
Gross profit, excluding intangible asset amortization	$ 3,690	$ 3,788	$ 11,474	$ 11,120
Gross margin	46.4 %	50.2 %	47.3 %	49.7 %
Gross margin, excluding intangible asset amortization	60.2 %	64.8 %	60.8 %	64.4 %