



## Pacira to buy Myoscience for up to \$220M

By Liz Hollis, Staff Writer

Pacira Pharmaceuticals Inc., of Parsippany, N.J., said it will scoop up Fremont, Calif.-based Myoscience Inc., which markets the lovera system as a nonopioid treatment that alleviates pain through cryoanalgesia. Pacira will make an initial payment of \$120 million, and Myoscience will be eligible to receive up to an additional \$100 million upon achievement of certain regulatory and commercial milestones.

Upon the completion of the transaction, which is expected by early April, Pacira intends to change its corporate name to Pacira Biosciences Inc., to demonstrate its expanding portfolio of nonopioid pain

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## FDA gives nod to real-time monitor to detect endovascular procedure bleeds from Saranas

By Stacy Lawrence, Staff Writer

Houston-based startup Saranas Inc. won a de novo designation from the U.S. FDA for its Early Bird bleed monitoring system. That makes it the first such real-time monitor for use during

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## Gottlieb to leave FDA after two-year tenure

By Mari Serebrov, Regulatory Editor

In a surprise announcement Tuesday, Scott Gottlieb said he was resigning as FDA commissioner, effective in one month.

His resignation letter included a list of FDA achievements during his nearly two-year tenure as head of the agency, but it gave no reason for his resignation. Just two months ago, Gottlieb

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## FDA panel says reduced drug use a valid endpoint in device hypertension

By Mark McCarty, Regulatory Editor

The field of device treatment for hypertension is still in its infancy, prompting the U.S. FDA to hold an advisory committee hearing to discuss clinical trials for such devices. While the panel endorsed the use of shams in pivotal trials, there

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## Ixico to boost diagnostic algorithms in UK via government partnership

By Nuala Moran, Staff Writer

LONDON – Ixico plc is poised to boost the power of its diagnostic algorithms as a partner in a new government-funded center applying digital imaging and artificial intelligence (AI) to the treatment and management of patients at hospitals in London.

The London Medical Imaging and Artificial Intelligence Center for Value-Based Healthcare, led by King's College London and based at St Thomas' Hospital, opened last week. It is one of five such centers around the U.K. established with

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## Ascendis' escape velocity liberating hGH daily users, phase III hits Height point

By Randy Osborne, Staff Writer

CEO Jan Møller Mikkelsen said Ascendis Pharma A/S is "still analyzing a lot of the data" from its phase III trial with its Transcon human growth hormone (hGH), a weekly therapy that beat daily growth hormone in the experiment called Height,

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### BioWorld MedTech's Oncology Extra

Regulatory Editor Mark McCarty and Senior Science Editor Anette Breindl on one of med-tech's key sectors

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## Pacira

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management and regenerative health solutions. Myoscience will become Pacira Cryotech Inc.

“This agreement represents an exciting accomplishment for the Myoscience team, and is good news for patients and physicians. We are confident that Pacira is the ideal organization to bring this technology to more physicians and their patients in need of effective nonopioid pain relief,” said Tim Still, president and CEO of Myoscience. “We are proud of the impact our technology has made, and we are excited to see Iovera reach its full potential as part of the Pacira portfolio.”

The announcement comes a week after Myoscience reported the commercial launch of the Iovera Smart Tip 309 for its system, which treats the genicular nerves through a process called cryoneurolysis. (See *BioWorld MedTech*, Feb. 28, 2019.) Specifically, it helps patients recovering from total knee arthroplasty surgery, as well as those suffering from chronic knee pain. The latest smart tip will help a broader patient population, including those with a high body mass index.

“We don’t really have direct competition,” Still told *BioWorld MedTech* at the time. “The primary purpose is to reduce the use of opioids and [the] pain that’s associated with surgery, recovery and chronic conditions.”

### Boosting its position

Also last week, David Stack, chair and CEO of Pacira Pharmaceuticals, said during the fourth-quarter earnings call that the company planned to boost its leadership position through partnerships and acquisitions. His company markets Exparel (bupivacaine liposome injectable suspension), which is a local analgesic administered at the time of surgery to control pain and reduce or eliminate the use of opioids for acute postsurgical pain.

In early February, Pacira reported that commercial production of the product is underway at a custom suite in Swindon, U.K. created under the company’s partnership with Thermo Fisher Scientific Pharma Services. The partners are developing a second dedicated suite that is expected to enable another doubling of Exparel manufacturing capacity in about two years.

With this buy, Stack said the Iovera system will boost his company’s position in nonopioid pain management by giving clinicians the only multimodal procedural solution for total knee arthroplasty procedures.

“With Exparel now firmly on a strong growth trajectory, our [Johnson & Johnson (J&J)] partnership and full stride, continued strong growth from our nerve block indication and increasing traction every day from the . . . implementation of C and D reimbursement codes, this is a right time for Pacira to begin our evolution from a single-product company to a leading provider of nonopioid pain management and regenerative health solutions,” Stack said during call on the acquisition. He noted that the buy was a huge step in that direction.

In early 2017, J&J’s Depuy Synthes Companies reported an exclusive agreement in the U.S. between Depuy Synthes Sales Inc. and Pacira to co-promote Exparel.

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*In sum, we have significant confidence in the value creation offered by this acquisition as Iovera is synergistic and is parallel to Exparel, offering health care providers an effective nonopioid multimodal regimen for pain management.*

David Stack

Chair and CEO, Pacira Pharmaceuticals Inc.

### Looking ahead

Stack also heralded the Iovera technology, noting that more than 20,000 patients have been treated with it so far. He added that the company intends to file for regulatory nods for the system in Europe and Canada later this year.

“[W]e have the capability and the capacity to deliver Iovera to more patients and accelerate growth in the short term, while we develop additional procedural solutions,” Stack said. “In sum, we have significant confidence in the value creation offered by this acquisition as Iovera is synergistic and is parallel to Exparel, offering health care providers an effective nonopioid multimodal regimen for pain management.”

He also expressed confidence that Iovera and Exparel combined with Tylenol ultimately will be the preferred nonopioid, multimodal procedure solution for stakeholders. “Iovera also optimizes resources, as it can be administered by physician extenders, such as physicians’ assistants and nurse practitioners and the site of care can be either the hospital, the ambulatories, surgical center or physician’s office. So it’s very easy to incorporate into the workflow of your practices as a new revenue generator,” he added.

Dana Flanders of Goldman Sachs Group Inc. asked about bundling during the call. “[I]t’s one of the places where we have a lot to learn from our partners at [J&J] about devices in general, but also about bundling. They have a lot more experience here. . . . So yes, we do see an opportunity to bundle.” Stack said, adding that it’s too early to really say how that will look. ♦

### Appointments and advancements

**Cerus Corp.**, of Concord, Calif., appointed Jami Nachtsheim to its board. Nachtsheim currently serves on the board at Intuitive Surgical. In addition, Laurence Corash has chosen not to stand for re-election to the board at the company’s 2019 annual stockholder meeting.

**Fempulse Corp.**, of Minneapolis, appointed Rob Kieval as chief scientific and chief clinical officer. He will assist in bringing treatments for overactive bladder to market. Kieval was the founder and CEO of CvrX, developer of a barostimulation device for hypertension.

**Fluidigm Corp.**, of South San Francisco, brought on Colin McCracken as chief commercial officer, a position he takes after serving as the VP for chromatography and mass spectrometry at Thermo Fisher Scientific.